## **SENATE BILL 720**

J3 8lr2519 CF HB 580

By: Senators Klausmeier and Della, Della, Exum, Garagiola, and Pugh

Introduced and read first time: February 1, 2008

Assigned to: Finance

Committee Report: Favorable with amendments

Senate action: Adopted

Read second time: March 20, 2008

CHAPTER \_\_\_\_\_

1 AN ACT concerning

## Pharmacy Benefits Managers - Pharmacy and Therapeutics Committees Committees

- 4 FOR the purpose of establishing certain requirements for members of a pharmacy and therapeutics committee of a pharmacy benefits manager; requiring a pharmacy 5 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 pharmacy and therapeutics committee; authorizing the Maryland Insurance 11 Commissioner to adopt certain regulations; making certain provisions of law 12 13 applicable to health maintenance organizations; defining certain terms; and generally relating to regulation of pharmacy benefits managers. 14
- 15 BY adding to
- 16 Article Insurance
- 17 Section 15–1601 and 15–1602 to be under the new subtitle "Subtitle 16.
- 18 Pharmacy Benefits Managers"
- 19 Annotated Code of Maryland
- 20 (2006 Replacement Volume and 2007 Supplement)
- 21 BY adding to
- 22 Article Health General
- 23 Section 19–706(ppp)
- 24 Annotated Code of Maryland

## EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.

<u>Underlining</u> indicates amendments to bill.

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



1	(2005 Replacement Volume and 2007 Supplement)
2 3	SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:
4	Article - Insurance
5	SUBTITLE 16. PHARMACY BENEFITS MANAGERS.
6	<del>15-1601.</del>
O	<del>10−10∪1,</del>
7 8	(A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE MEANINGS INDICATED.
9	(2) (1) "PHARMACY BENEFITS MANAGEMENT SERVICES"
10	MEANS THE ADMINISTRATION OR MANAGEMENT OF PRESCRIPTION DRUG
11	BENEFITS.
12	(11) "DILADRIA CIV DENDERUDO NA ANA CIENZIDAD CEDIVICIOS"
13	(H) "PHARMACY BENEFITS MANAGEMENT SERVICES"
10	<del>INCLUDES:</del>
14	1. PROCUREMENT OF PRESCRIPTION DRUGS AT A
15	NEGOTIATED RATE FOR DISPENSATION WITHIN THE STATE;
16	2. PROCESSING OF PRESCRIPTION DRUG CLAIMS;
17	0
17	3. ADMINISTRATION OF PAYMENTS RELATED TO
18	PRESCRIPTION DRUG CLAIMS; AND
19	4. NEGOTIATING OR ENTERING INTO CONTRACTUAL
20	ARRANGEMENTS WITH PHARMACY PROVIDERS.
21	(3) "Pharmacy benefits manager" means a person that
22	PERFORMS PHARMACY BENEFITS MANAGEMENT SERVICES.
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23	(B) THE PROVISIONS OF THIS SECTION DO NOT APPLY TO A MANAGED
24	CARE ORGANIZATION AUTHORIZED BY TITLE 15, SUBTITLE 1 OF THE HEALTH-
25	GENERAL ARTICLE.
26	(c) The provisions of this section do not apply to an insurer,
27	NONPROFIT HEALTH SERVICE PLAN, OR HEALTH MAINTENANCE ORGANIZATION
28	OR AN AFFILIATE, SUBSIDIARY, OR OTHER RELATED ENTITY OF AN INSURER.
29	NONPROFIT HEALTH SERVICE PLAN, OR HEALTH MAINTENANCE ORGANIZATION
30	ACTING OR REPRESENTING ITSELF AS A PHARMACY BENEFITS MANAGER IF:

1	(1)
1	(1) THE INSURER, NONPROFIT HEALTH SERVICE PLAN, OR
2	HEALTH MAINTENANCE ORGANIZATION OR THE AFFILIATE, SUBSIDIARY, OR
3	OTHER RELATED ENTITY OF THE INSURER, NONPROFIT HEALTH SERVICE PLAN,
4	OR HEALTH MAINTENANCE ORGANIZATION DIRECTLY OFFERS OR PROVIDES
5	PHARMACY BENEFITS MANAGEMENT SERVICES; AND
6	(2) THE PHARMACY BENEFITS MANAGEMENT SERVICES ARE
7	OFFERED OR PROVIDED ONLY TO ENROLLEES, SUBSCRIBERS, OR INSUREDS
8	WHO ALSO ARE COVERED BY HEALTH BENEFITS OFFERED OR PROVIDED BY THE
9	INSURER, NONPROFIT HEALTH SERVICE PLAN, OR HEALTH MAINTENANCE
10	ORGANIZATION.
11	(D) (1) EACH MEMBER OF A PHARMACY AND THERAPEUTICS
12	COMMITTEE OF A PHARMACY BENEFITS MANAGER SHALL BE:
13	(I) A PHYSICIAN OR OTHER AUTHORIZED PRESCRIBER, A
14	PHARMACIST, OR A FACULTY MEMBER OF AN ACADEMIC MEDICAL CENTER; AND
15	(II) DISCLOSED BY NAME TO THE PURCHASER ON REQUEST.
16	(2) A MAJORITY OF COMMITTEE MEMBERS MAY NOT BE
17	EMPLOYED BY THE PHARMACY BENEFITS MANAGER.
18	(E) A PHARMACY AND THERAPEUTICS COMMITTEE MEMBER MAY NOT:
19	(1) BE AN OFFICER, EMPLOYEE, DIRECTOR, OR AGENT OF A
20	PHARMACEUTICAL MANUFACTURER; OR
21	(2) HAVE A FINANCIAL INTEREST IN A PHARMACEUTICAL
22	MANUFACTURER, OTHER THAN OWNERSHIP OF A NOMINAL NUMBER OF SHARES
23	OF THE PHARMACEUTICAL MANUFACTURER'S STOCK, PURCHASED ON A
24	NATIONAL SECURITIES EXCHANGE.
25	(F) (1) A PHARMACY BENEFITS MANAGER MAY NOT REQUIRE A
26	PHARMACY TO PARTICIPATE IN A PHARMACY AND THERAPEUTICS COMMITTEE.
27	(2) IF A PHARMACY AGREES TO PARTICIPATE IN A PHARMACY
28	AND THERAPEUTICS COMMITTEE, THE PHARMACY BENEFITS MANAGER SHALL
29	REIMBURSE ANY EXPENSES INCURRED BY THE PHARMACY AS A RESULT OF ITS
30	PARTICIPATION.
31	<u>15–1601.</u>
32	(A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS

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INDICATED.

${1 \atop 2}$	(B) "BENEFICIARY" MEANS AN INDIVIDUAL WHO RECEIVES
Z	PRESCRIPTION DRUG COVERAGE OR BENEFITS FROM A PURCHASER.
3	(C) "ERISA" HAS THE MEANING STATED IN § 8–301 OF THIS ARTICLE.
4	(D) "FORMULARY" MEANS A LIST OF PRESCRIPTION DRUGS USED BY A
5	PURCHASER.
$\frac{6}{7}$	(E) "NONPROFIT HEALTH MAINTENANCE ORGANIZATION" HAS THE
1	MEANING STATED IN § 6–121(A) OF THIS ARTICLE.
8	(F) (1) "PHARMACY BENEFITS MANAGEMENT SERVICES" MEANS:
9	(I) THE PROCUREMENT OF PRESCRIPTION DRUGS AT A
10	NEGOTIATED RATE FOR DISPENSATION WITHIN THE STATE TO BENEFICIARIES;
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11 12	(II) THE ADMINISTRATION OR MANAGEMENT OF PRESCRIPTION DRUG COVERAGE PROVIDED BY A PURCHASER FOR
13	BENEFICIARIES; AND
	<del></del>
14	(III) ANY OF THE FOLLOWING SERVICES PROVIDED WITH
15	REGARD TO THE ADMINISTRATION OF PRESCRIPTION DRUG COVERAGE:
16	1. MAIL SERVICE PHARMACY;
17	2. CLAIMS PROCESSING, RETAIL NETWORK
18	MANAGEMENT AND PAYMENT OF CLAIMS TO PHARMACIES FOR PRESCRIPTION
19	DRUGS DISPENSED TO BENEFICIARIES;
20	9 CLINICAL EQUINITIADIZ DEVELODIMENTI AND
$\frac{20}{21}$	3. <u>CLINICAL FORMULARY DEVELOPMENT AND</u> MANAGEMENT SERVICES;
	MANAGEMENT SERVICES;
22	4. REBATE CONTRACTING AND ADMINISTRATION;
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<ul><li>23</li><li>24</li></ul>	5. PATIENT COMPLIANCE, THERAPEUTIC
44	INTERVENTION, AND GENERIC SUBSTITUTION PROGRAMS; OR
25	6. DISEASE MANAGEMENT PROGRAMS.
26	(2) "PHARMACY BENEFITS MANAGEMENT SERVICES" DOES NOT
27	INCLUDE ANY SERVICE PROVIDED BY A NONPROFIT HEALTH MAINTENANCE
28	ORGANIZATION THAT OPERATES AS A GROUP MODEL, PROVIDED THAT THE
29	SERVICE:

$rac{1}{2}$	(I) IS PROVIDED SOLELY TO A MEMBER OF THE NONPROFIT
2	HEALTH MAINTENANCE ORGANIZATION; AND
3	(II) IS FURNISHED THROUGH THE INTERNAL PHARMACY
4	OPERATIONS OF THE NONPROFIT HEALTH MAINTENANCE ORGANIZATION.
5	(G) "PHARMACY BENEFITS MANAGER" MEANS A PERSON THAT
6	PERFORMS PHARMACY BENEFITS MANAGEMENT SERVICES.
7	(H) "PHARMACY AND THERAPEUTICS COMMITTEE" MEANS A
8	COMMITTEE ESTABLISHED BY A PHARMACY BENEFITS MANAGER TO:
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9	(1) OBJECTIVELY APPRAISE AND EVALUATE PRESCRIPTION
10	DRUGS; AND
11	
11	(2) MAKE RECOMMENDATIONS TO A PURCHASER REGARDING THE
12	SELECTION OF DRUGS FOR THE PURCHASER'S FORMULARY.
13	(I) (1) "PURCHASER" MEANS THE STATE EMPLOYEE AND RETIREE
14	HEALTH AND WELFARE BENEFITS PROGRAM, AN INSURER, A NONPROFIT
15	HEALTH SERVICE PLAN, OR A HEALTH MAINTENANCE ORGANIZATION THAT:
10	HEALTH SERVICE PLAN, OR A HEALTH MAINTENANCE ORGANIZATION THAT:
16	(I) PROVIDES PRESCRIPTION DRUG COVERAGE OR
17	BENEFITS IN THE STATE; AND
18	(II) ENTERS INTO AN AGREEMENT WITH A PHARMACY
19	BENEFITS MANAGER FOR THE PROVISION OF PHARMACY BENEFITS
00	DENEFITS MANAGER FOR THE PROVISION OF PHARMACT DENEFITS
20	MANAGEMENT SERVICES.
	MANAGEMENT SERVICES.
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21 22	MANAGEMENT SERVICES.
21 22 23	MANAGEMENT SERVICES.  (2) "PURCHASER" DOES NOT INCLUDE A PERSON THAT PROVIDES
21 22 23 24	MANAGEMENT SERVICES.  (2) "PURCHASER" DOES NOT INCLUDE A PERSON THAT PROVIDES PRESCRIPTION DRUG COVERAGE OR BENEFITS THROUGH PLANS SUBJECT TO
21 22 23	MANAGEMENT SERVICES.  (2) "PURCHASER" DOES NOT INCLUDE A PERSON THAT PROVIDES PRESCRIPTION DRUG COVERAGE OR BENEFITS THROUGH PLANS SUBJECT TO ERISA AND DOES NOT PROVIDE PRESCRIPTION DRUG COVERAGE OR BENEFITS
21 22 23 24 25	(2) "PURCHASER" DOES NOT INCLUDE A PERSON THAT PROVIDES PRESCRIPTION DRUG COVERAGE OR BENEFITS THROUGH PLANS SUBJECT TO ERISA AND DOES NOT PROVIDE PRESCRIPTION DRUG COVERAGE OR BENEFITS THROUGH INSURANCE, UNLESS THE PERSON IS A MULTIPLE EMPLOYER WELFARE ARRANGEMENT AS DEFINED IN § 514(B)(6)(A)(II) OF ERISA.
21 22 23 24	(2) "PURCHASER" DOES NOT INCLUDE A PERSON THAT PROVIDES PRESCRIPTION DRUG COVERAGE OR BENEFITS THROUGH PLANS SUBJECT TO ERISA AND DOES NOT PROVIDE PRESCRIPTION DRUG COVERAGE OR BENEFITS THROUGH INSURANCE, UNLESS THE PERSON IS A MULTIPLE EMPLOYER
21 22 23 24 25	(2) "PURCHASER" DOES NOT INCLUDE A PERSON THAT PROVIDES PRESCRIPTION DRUG COVERAGE OR BENEFITS THROUGH PLANS SUBJECT TO ERISA AND DOES NOT PROVIDE PRESCRIPTION DRUG COVERAGE OR BENEFITS THROUGH INSURANCE, UNLESS THE PERSON IS A MULTIPLE EMPLOYER WELFARE ARRANGEMENT AS DEFINED IN § 514(B)(6)(A)(II) OF ERISA.  15–1602.
21 22 23 24 25 26	(2) "PURCHASER" DOES NOT INCLUDE A PERSON THAT PROVIDES PRESCRIPTION DRUG COVERAGE OR BENEFITS THROUGH PLANS SUBJECT TO ERISA AND DOES NOT PROVIDE PRESCRIPTION DRUG COVERAGE OR BENEFITS THROUGH INSURANCE, UNLESS THE PERSON IS A MULTIPLE EMPLOYER WELFARE ARRANGEMENT AS DEFINED IN § 514(B)(6)(A)(II) OF ERISA.  15–1602.  (A) A PHARMACY AND THERAPEUTICS COMMITTEE ESTABLISHED BY A
21 22 23 24 25 26 27 28	(2) "PURCHASER" DOES NOT INCLUDE A PERSON THAT PROVIDES PRESCRIPTION DRUG COVERAGE OR BENEFITS THROUGH PLANS SUBJECT TO ERISA AND DOES NOT PROVIDE PRESCRIPTION DRUG COVERAGE OR BENEFITS THROUGH INSURANCE, UNLESS THE PERSON IS A MULTIPLE EMPLOYER WELFARE ARRANGEMENT AS DEFINED IN § 514(B)(6)(A)(II) OF ERISA.  15–1602.  (A) A PHARMACY AND THERAPEUTICS COMMITTEE ESTABLISHED BY A PHARMACY BENEFITS MANAGER SHALL MEET THE REQUIREMENTS OF THIS
21 22 23 24 25 26	(2) "PURCHASER" DOES NOT INCLUDE A PERSON THAT PROVIDES PRESCRIPTION DRUG COVERAGE OR BENEFITS THROUGH PLANS SUBJECT TO ERISA AND DOES NOT PROVIDE PRESCRIPTION DRUG COVERAGE OR BENEFITS THROUGH INSURANCE, UNLESS THE PERSON IS A MULTIPLE EMPLOYER WELFARE ARRANGEMENT AS DEFINED IN § 514(B)(6)(A)(II) OF ERISA.  15–1602.  (A) A PHARMACY AND THERAPEUTICS COMMITTEE ESTABLISHED BY A
21 22 23 24 25 26 27 28 29	(2) "PURCHASER" DOES NOT INCLUDE A PERSON THAT PROVIDES PRESCRIPTION DRUG COVERAGE OR BENEFITS THROUGH PLANS SUBJECT TO ERISA AND DOES NOT PROVIDE PRESCRIPTION DRUG COVERAGE OR BENEFITS THROUGH INSURANCE, UNLESS THE PERSON IS A MULTIPLE EMPLOYER WELFARE ARRANGEMENT AS DEFINED IN § 514(B)(6)(A)(II) OF ERISA.  15–1602.  (A) A PHARMACY AND THERAPEUTICS COMMITTEE ESTABLISHED BY A PHARMACY BENEFITS MANAGER SHALL MEET THE REQUIREMENTS OF THIS SECTION.
21 22 23 24 25 26 27 28	(2) "PURCHASER" DOES NOT INCLUDE A PERSON THAT PROVIDES PRESCRIPTION DRUG COVERAGE OR BENEFITS THROUGH PLANS SUBJECT TO ERISA AND DOES NOT PROVIDE PRESCRIPTION DRUG COVERAGE OR BENEFITS THROUGH INSURANCE, UNLESS THE PERSON IS A MULTIPLE EMPLOYER WELFARE ARRANGEMENT AS DEFINED IN § 514(B)(6)(A)(II) OF ERISA.  15–1602.  (A) A PHARMACY AND THERAPEUTICS COMMITTEE ESTABLISHED BY A PHARMACY BENEFITS MANAGER SHALL MEET THE REQUIREMENTS OF THIS

NEEDS OF A PURCHASER'S BENEFICIARIES; AND

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1	(II) INCLUDE AT LEAST ONE PRACTICING PHARMACIST AND
2	ONE PRACTICING PHYSICIAN WHO ARE INDEPENDENT OF ANY DEVELOPER OF
3	MANUFACTURER OF PRESCRIPTION DRUGS.
4	(2) EACH MEMBER OF A PHARMACY AND THERAPEUTICS
5	COMMITTEE SHALL SIGN A CONFLICT OF INTEREST STATEMENT UPDATED AT
6	LEAST ANNUALLY DISCLOSING ANY ECONOMIC INTEREST OR RELATIONSHIP
7	THAT COULD INFLUENCE THE PHARMACY AND THERAPEUTICS COMMITTEE'S
8	DECISIONS.
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9	(3) A MAJORITY OF THE MEMBERS OF A PHARMACY AND
10 11	THERAPEUTICS COMMITTEE SHALL BE PRACTICING PHYSICIANS OF
11	PRACTICING PHARMACISTS.
12	(C) A PHARMACY BENEFITS MANAGER SHALL ENSURE THAT ITS
13	PHARMACY AND THERAPEUTICS COMMITTEE HAS:
10	I HARMACI AND THERAI ECTIOS COMMITTEE HAS.
14	(1) POLICIES AND PROCEDURES, INCLUDING DISCLOSURE
15	REQUIREMENTS, TO ADDRESS POTENTIAL CONFLICTS OF INTEREST THAT
16	MEMBERS OF THE PHARMACY AND THERAPEUTICS COMMITTEE MAY HAVE WITH
17	DEVELOPERS OR MANUFACTURERS OF PRESCRIPTION DRUGS;
18	(2) A PROCESS TO EVALUATE MEDICAL AND SCIENTIFIC
19	EVIDENCE CONCERNING THE SAFETY AND EFFECTIVENESS OF PRESCRIPTION
20	DRUGS, INCLUDING AVAILABLE COMPARATIVE INFORMATION ON CLINICALLY
21	SIMILAR PRESCRIPTION DRUGS, WHEN DECIDING WHAT PRESCRIPTION DRUGS
22	TO RECOMMEND TO INCLUDE ON A FORMULARY;
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23	(3) A PROCESS TO EVALUATE MEDICAL AND SCIENTIFIC
$\frac{24}{25}$	EVIDENCE CONCERNING THE SAFETY AND EFFECTIVENESS OF PRESCRIPTION
26	DRUGS WHEN RECOMMENDING UTILIZATION REVIEW REQUIREMENTS, DOSE
20	RESTRICTIONS, AND STEP THERAPY REQUIREMENTS; AND
27	(4) A PROCESS TO ENABLE THE PHARMACY AND THERAPEUTICS
28	COMMITTEE TO CONSIDER THE NEED TO RECOMMEND A FORMULARY CHANGE
29	TO A PURCHASER IN A TIMELY MANNER BUT AT LEAST ANNUALLY.
30	(D) THE COMMISSIONER MAY CONSIDER A PHARMACY AND
31	THERAPEUTICS COMMITTEE OF A PHARMACY BENEFITS MANAGER AS HAVING
32	MET THE REQUIREMENTS OF SUBSECTIONS (B) AND (C) OF THIS SECTION IF THE
33	PHARMACY BENEFITS MANAGER HAS OBTAINED ACCREDITATION FROM AN

ACCREDITING ORGANIZATION APPROVED BY THE COMMISSIONER.

${1 \atop 2}$	(E) ON REQUEST OF A PURCHASER FOR WHICH THE PHARMACY AND THERAPEUTICS COMMITTEE MAKES RECOMMENDATIONS, A PHARMACY
3	BENEFITS MANAGER SHALL DISCLOSE INFORMATION ABOUT THE COMPOSITION
4	OF ITS PHARMACY AND THERAPEUTICS COMMITTEE TO THE PURCHASER.
5 6 7	(F) A PHARMACY BENEFITS MANAGER MAY NOT REQUIRE A PHARMACIST TO PARTICIPATE ON ITS PHARMACY AND THERAPEUTICS COMMITTEE.
8 9	(G) ON OR BEFORE APRIL 1, 2009, THE THE COMMISSIONER SHALL MAY ADOPT REGULATIONS TO IMPLEMENT THIS SECTION.
10 11	(H) THE COMMISSIONER MAY ASSESS A CIVIL PENALTY NOT EXCEEDING \$5,000 FOR EACH VIOLATION OF THIS SECTION.
12	Article – Health – General
13	19–706.
14 15	(PPP) THE PROVISIONS OF $\S$ 15–1601 OF THE INSURANCE ARTICLE APPLY TO HEALTH MAINTENANCE ORGANIZATIONS.
16 17	SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2008.
	Approved:
	Governor.
	President of the Senate.
	Speaker of the House of Delegates.