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Introduced and read first time: January 29, 2004 Assigned to: Health and Government Operations

Committee Report: Favorable with amendments House action: Adopted Read second time: March 16, 2004

CHAPTER_____

1 AN ACT concerning

2

Task Force to Study Pharmacy Benefits Management Act

3 FOR the purpose of prohibiting a person from practicing pharmacy benefits 4 management in the State unless the person registers with the Secretary of 5 Health and Mental Hygiene; requiring an applicant to file a certain application, 6 submit certain documents, and pay a certain fee; providing for the term of the 7 registration; providing for the renewal of a registration; authorizing the 8 Secretary to suspend or revoke a registration or deny an application under 9 certain circumstances; providing for a certain notice and hearing before a 10 refusal to renew a registration; providing for an appeal to the Health Claims Arbitration Office; establishing that a pharmacy benefits manager is a fiduciary 11 12 and is required to conform to certain standards of conduct; prohibiting a 13 pharmacy benefits manager from acting as a private review agent under certain 14 circumstances; requiring a pharmacy benefits manager to perform duties for a 15 certain purpose and to disclose certain information regarding any conflicts of 16 interest; requiring a pharmacy benefits manager to provide certain financial 17 and utilization information requested by a covered entity; permitting a pharmacy benefits manager to designate certain information as confidential; 18 19 providing for the release of certain confidential information by a covered entity 20 from a pharmacy benefits manager under certain circumstances; requiring a pharmacy benefits manager to dispense certain prescription drugs in a certain 21 22 manner; requiring a pharmacy benefits manager to transfer certain benefits or

- 1 payments received to the covered entity under certain circumstances; providing
- 2 for a civil penalty; and generally relating to the registration and regulation of
- 3 pharmacy benefits managers.

4 FOR the purpose of establishing a Task Force to Study Pharmacy Benefits

- 5 Management; providing for the membership, staffing, and reimbursement of
- 6 expenses of the Task Force; requiring the Task Force to study regulation of
- 7 pharmacy benefits managers; specifying items to be included in the study;
- 8 requiring the Task Force to recommend draft legislation; requiring the Task
- 9 Force to report its findings and draft legislation, in accordance with certain
- 10 provisions of the State Government Article, to the Senate Finance Committee
- 11 and House Health and Government Operations Committee on or before a
- 12 certain date; and generally relating to a Task Force to Study Pharmacy Benefits
- 13 <u>Management.</u>

14 BY adding to

- 15 Article Health General
- Section 20 1001 through 20 1009, inclusive, to be under the new subtitle
 "Subtitle 10. Pharmacy Benefits Management Act"
- 18 Annotated Code of Maryland
- 19 (2000 Replacement Volume and 2003 Supplement)
- 20 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF
- 21 MARYLAND, That the Laws of Maryland read as follows:

22	Article	- Health -	- General

23

SUBTITLE 10. PHARMACY BENEFITS MANAGEMENT ACT.

24 20 1001.

25 (A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS
 26 INDICATED.

27 (B) (1) "COVERED ENTITY" MEANS A PERSON THAT OFFERS HEALTH
 28 INSURANCE THAT INCLUDES PRESCRIPTION DRUG AND DEVICE SERVICES TO THE
 29 PLAN'S ENROLLEES.

30(2)"COVERED ENTITY" INCLUDES SELF-INSURED EMPLOYERS,31INSURERS, UNIONS, AND HEALTH MAINTENANCE ORGANIZATIONS.

32 (C) "ENROLLEE" MEANS A MEMBER, PARTICIPANT, CONTRACT HOLDER,
 33 POLICYHOLDER, OR BENEFICIARY OF A COVERED ENTITY.

34 (D) "GENERIC DRUG" MEANS A CHEMICALLY EQUIVALENT COPY OF A
 35 BRAND-NAME DRUG WITH AN EXPIRED PATENT.

36(E)"LABELER" MEANS A PERSON THAT RECEIVES PRESCRIPTION DRUGS37FROM A MANUFACTURER OR WHOLESALER AND REPACKAGES THE DRUGS FOR

3 HOUSE BILL 397			
1 LATER RETAIL SALE AND HAS A LABELER CODE FROM THE FEDERAL FOOD AND 2 DRUG ADMINISTRATION UNDER 21 C.F.R. 270.20 (1999).	L		
3 (F) "PHARMACY" HAS THE MEANING STATED IN § 12-101 OF THE HEALTH 4 OCCUPATIONS ARTICLE.			
5 (G) "PHARMACY BENEFITS MANAGEMENT" MEANS:			
6 (1) THE PROCUREMENT OF PRESCRIPTION DRUGS AT A NEGOTIA 7 RATE FOR DISPENSING WITHIN THIS STATE TO ENROLLEES;	TED		
8 (2) THE ADMINISTRATION OR MANAGEMENT OF PRESCRIPTION I 9 BENEFITS PROVIDED BY A COVERED ENTITY FOR THE BENEFIT OF ENROLLEES; (
10 (3) THE ADMINISTRATION OF ANY OF THE FOLLOWING SERVICE: 11 RELATED TO PHARMACY BENEFITS:	5		
12 (I) MAIL SERVICE PHARMACY;			
13(II)CLAIMS PROCESSING, RETAIL NETWORK MANAGEMENT14PAYMENT OF CLAIMS TO PHARMACIES FOR PRESCRIPTION DRUGS DISPENSED T15COVERED INDIVIDUALS;			
16 (III) CLINICAL FORMULARY DEVELOPMENT AND MANAGE 17 SERVICES;	MENT		
18 (IV) REBATE CONTRACTING AND ADMINISTRATION;			
19 (V) CERTAIN PATIENT COMPLIANCE, THERAPEUTIC 20 INTERVENTION, AND GENERIC DRUG SUBSTITUTION PROGRAMS; AND			
21 (VI) DISEASE MANAGEMENT PROGRAMS.			
 22 (H) "PHARMACY BENEFITS MANAGER" OR "PBM" MEANS A PERSON THAT 23 PERFORMS PHARMACY BENEFITS MANAGEMENT IN A CONTRACTUAL OR 24 EMPLOYMENT RELATIONSHIP FOR A COVERED ENTITY. 	F		
25 (I) "PRIVATE REVIEW AGENT" MEANS A PRIVATE REVIEW AGENT REGU 26 UNDER SUBTITLE 10B OF THE INSURANCE ARTICLE.	LATED		
27 20 1002.			
28 (A) A PERSON MAY NOT ENGAGE IN PHARMACY BENEFITS MANAGEMEN 29 THE STATE UNLESS THE PERSON REGISTERS WITH THE SECRETARY.	T IN		
30 (B) AN APPLICANT FOR REGISTRATION SHALL:			
31 (1) SUBMIT TO THE SECRETARY AN APPLICATION ON THE FORM 32 THE SECRETARY PROVIDES;	THAT		
33 (2) SUBMIT THE DOCUMENTS THAT THE SECRETARY REQUIRES;	AND		

1 2 SECRETAI	(3) RY.	PAY TO THE SECRETARY AN APPLICATION FEE SET BY THE
3 (C) 4 REQUIREN		ECRETARY SHALL REGISTER EACH APPLICANT THAT MEETS THE OF THIS SECTION.
5 (D) 6 SECRETAI		ECRETARY SHALL INCLUDE ON EACH REGISTRATION THAT THE ES:
7	(1)	THE FULL NAME OF THE REGISTRANT;
8	(2)	THE LEGAL NAME OF THE BUSINESS;
9	(3)	THE CURRENT ADDRESS OF THE REGISTRANT;
10	(4)	THE DATE OF ISSUANCE OF THE REGISTRATION; AND

12 (E) EACH REGISTRANT SHALL GIVE THE SECRETARY WRITTEN NOTICE OF 13 ANY CHANGE OF ADDRESS WITHIN 10 BUSINESS DAYS AFTER THE CHANGE.

THE DATE THE REGISTRATION EXPIRES.

14 (F) (1) UNLESS A REGISTRATION IS RENEWED FOR A 4-YEAR TERM AS 15 PROVIDED IN THIS SECTION, THE REGISTRATION EXPIRES ON JUNE 1 OF THE FIRST

16 ODD NUMBERED YEAR AFTER THE EFFECTIVE DATE OF THE REGISTRATION.

17(2)AT LEAST 1 MONTH BEFORE A REGISTRATION EXPIRES, THE18SECRETARY SHALL MAIL TO THE REGISTRANT:

19 (I) A RENEWAL APPLICATION FORM; AND

20 (II) A NOTICE THAT STATES:

211.THE DATE ON WHICH THE CURRENT REGISTRATION22 EXPIRES;

23 2. THE DATE BY WHICH THE SECRETARY MUST RECEIVE
 24 THE RENEWAL APPLICATION FOR THE RENEWAL TO BE ISSUED AND MAILED BEFORE
 25 THE REGISTRATION EXPIRES; AND

26 3. THE AMOUNT OF THE RENEWAL FEE.

27 (3) BEFORE THE REGISTRATION EXPIRES, THE REGISTRANT MAY
 28 PERIODICALLY RENEW FOR AN ADDITIONAL 4 YEAR TERM, IF THE REGISTRANT:

29 (I) OTHERWISE IS ENTITLED TO BE REGISTERED; AND

30 (II) PAYS TO THE SECRETARY A RENEWAL FEE AS SET BY THE

31 SECRETARY.

4

11

(5)

1 20 1003.

SUBJECT TO THE HEARING PROVISIONS OF SUBSECTION (C) OF THIS 2 (A)3 SECTION. THE SECRETARY MAY DENY REGISTRATION TO ANY APPLICANT. 4 REPRIMAND ANY REGISTRANT, FINE ANY REGISTRANT, OR SUSPEND OR REVOKE A 5 REGISTRATION IF THE APPLICANT OR REGISTRANT: FRAUDULENTLY OR DECEPTIVELY OBTAINS OR ATTEMPTS TO (1)6 7 OBTAIN A REGISTRATION FOR THE APPLICANT OR REGISTRANT OR FOR ANOTHER; 8 FRAUDULENTLY OR DECEPTIVELY USES A REGISTRATION; (2)9 (3)HAS A SIMILAR LICENSE OR REGISTRATION DENIED. SUSPENDED, OR 10 REVOKED IN ANOTHER JURISDICTION: 11 (4)PLEADS GUILTY OR NOLO CONTENDERE TO OR IS CONVICTED OF A 12 FELONY. THEFT OFFENSE. OR CRIME OF MORAL TURPITUDE: AIDS AN INDIVIDUAL IN FRAUDULENTLY OR DECEPTIVELY 13 (5)14 OBTAINING OR ATTEMPTING TO OBTAIN A REGISTRATION UNDER THIS TITLE;

15 (6) WHILE NOT REGISTERED AS A PBM AND EMPLOYED BY OR UNDER
 16 CONTRACT WITH A COVERED ENTITY, SOLICITS TO ENGAGE IN OR WILLFULLY
 17 ENGAGES IN PHARMACY BENEFITS MANAGEMENT;

18(7)WHILE NOT REGISTERED AS A PBM AND EMPLOYED BY OR UNDER19CONTRACT WITH A COVERED ENTITY, WILLFULLY ADVERTISES AS A PBM;

20 (8) WILLFULLY MAKES A FALSE STATEMENT OR MISREPRESENTATION
 21 IN ANY RENEWAL APPLICATION OR IN ANY OTHER DOCUMENT THAT THE
 22 SECRETARY REQUIRES TO BE SUBMITTED; OR

23 (9) VIOLATES ANY OTHER PROVISION OF THIS SUBTITLE.

24 (B) BEFORE THE SECRETARY DENIES THE REGISTRATION OF AN APPLICANT
 25 UNDER SUBSECTION (A) OF THIS SECTION, THE SECRETARY SHALL CONSIDER THE
 26 FOLLOWING FACTORS:

27 (1) THE LENGTH OF TIME THAT HAS PASSED SINCE THE APPLICANT
 28 PLEADED GUILTY OR NOLO CONTENDERE OR WAS CONVICTED OF THE FELONY,
 29 THEFT OFFENSE, OR CRIME OF MORAL TURPITUDE;

30(2)WHETHER THE APPLICANT WAS A PBM PRIOR TO THE REQUIREMENT31OF REGISTRATION UNDER THIS SUBTITLE; AND

32 (3) ANY EVIDENCE THAT THE APPLICANT HAS BEEN A GOOD CITIZEN
 33 SINCE THE APPLICANT PLEADED GUILTY OR NOLO CONTENDERE OR WAS
 34 CONVICTED OF THE FELONY, THEFT OFFENSE, OR CRIME OF MORAL TURPITUDE.

35 (C) (1) BEFORE THE SECRETARY TAKES ANY FINAL ACTION UNDER
 36 SUBSECTION (A) OF THIS SECTION, THE SECRETARY SHALL GIVE THE APPLICANT OR

1 REGISTRANT AGAINST WHOM THE ACTION IS CONTEMPLATED AN OPPORTUNITY FOR 2 A HEARING BEFORE THE SECRETARY.

3 (2) THE SECRETARY SHALL GIVE NOTICE AND HOLD THE HEARING IN
 4 ACCORDANCE WITH TITLE 10, SUBTITLE 2 OF THE STATE GOVERNMENT ARTICLE.

5 (3) THE HEARING NOTICE TO BE GIVEN TO THE APPLICANT OR
6 REGISTRANT SHALL BE SENT BY CERTIFIED MAIL TO THE LAST KNOWN ADDRESS OF
7 THE APPLICANT OR REGISTRANT AT LEAST 10 BUSINESS DAYS BEFORE THE
8 HEARING.

9 (4) THE SECRETARY MAY ADMINISTER OATHS IN CONNECTION WITH 10 ANY PROCEEDING UNDER THIS SECTION.

11(5)THE APPLICANT OR REGISTRANT MAY BE REPRESENTED AT THE12HEARING BY COUNSEL.

13 (6) IF, AFTER DUE NOTICE, THE APPLICANT OR REGISTRANT AGAINST
 14 WHOM THE ACTION IS CONTEMPLATED FAILS OR REFUSES TO APPEAR, THE
 15 SECRETARY MAY, NEVERTHELESS, HEAR AND DETERMINE THE MATTER.

16 (D) ANY APPLICANT OR REGISTRANT AGGRIEVED BY A FINAL DECISION OF
 17 THE SECRETARY MAY TAKE AN APPEAL TO THE HEALTH CLAIMS ARBITRATION
 18 OFFICE.

19 20-1004.

20 A PBM IS A FIDUCIARY AND SHALL ACT:

21 (1) IN GOOD FAITH;

22 (2) IN A MANNER THAT IS REASONABLY BELIEVED TO BE IN THE BEST
 23 INTEREST OF THE COVERED ENTITY AND THE COVERED ENTITY'S ENROLLEES;

24 (3) WITH CARE, SKILL, PRUDENCE, AND DILIGENCE; AND

25 (4) IN ACCORDANCE WITH THE STANDARDS OF CONDUCT APPLICABLE
 26 TO A FIDUCIARY IN AN ENTERPRISE OF LIKE CHARACTER AND WITH LIKE AIMS.

27 20-1005.

28 (A) A PBM SHALL:

29 (1) PERFORM ITS DUTIES FOR THE COVERED ENTITY FOR THE PURPOSE
 30 OF PROVIDING BENEFITS TO ENROLLEES AND DEFRAYING REASONABLE EXPENSES
 31 OF ADMINISTERING HEALTH SERVICES; AND

32 (2) DISCLOSE IN WRITING TO THE COVERED ENTITY ANY ACTIVITY,
 33 POLICY, OR PRACTICE THAT DIRECTLY OR INDIRECTLY PRESENTS ANY CONFLICT OF
 34 INTEREST WITH THE DUTIES IMPOSED BY THIS SUBTITLE.

1 (B) A PBM MAY NOT ACT AS A PRIVATE REVIEW AGENT WHILE PERFORMING 2 ITS DUTIES AS A PBM. 3 20-1006. A PBM SHALL PROVIDE TO THE COVERED ENTITY ALL FINANCIAL AND (A)Δ 5 UTILIZATION INFORMATION REQUESTED BY THE COVERED ENTITY RELATING TO: THE PROVISION OF BENEFITS TO ENROLLEES THROUGH THE (1)6 7 COVERED ENTITY: AND (2)ALL FINANCIAL AND UTILIZATION INFORMATION RELATING TO 8 9 SERVICES TO THE COVERED ENTITY. 10 (B) (1)THE PBM MAY DESIGNATE ANY FINANCIAL AND UTILIZATION 11 INFORMATION PROVIDED TO THE COVERED ENTITY BY THE PBM AS CONFIDENTIAL. (2)EXCEPT AS PROVIDED IN PARAGRAPH (3) OF THIS SUBSECTION. 12 13 CONFIDENTIAL INFORMATION PROVIDED TO A COVERED ENTITY BY A PBM MAY NOT 14 BE DISCLOSED BY THE COVERED ENTITY TO ANY PERSON WITHOUT THE WRITTEN 15 CONSENT OF THE PBM. A COVERED ENTITY MAY DISCLOSE INFORMATION DESCRIBED IN (3)16 17 PARAGRAPH (1) OF THIS SUBSECTION: TO THE EXTENT THAT DISCLOSURE MAY BE NECESSARY TO 18 (H)19 CARRY OUT THE PURPOSES OF THIS SUBTITLE; (II)WITH THE EXPRESS WRITTEN CONSENT OF THE PBM; 20 21 (III) UNDER STATUTE OR COURT ORDER FOR THE PRODUCTION OR 22 DISCOVERY OF EVIDENCE: OR (\mathbf{W}) IF THE INFORMATION IS PERTINENT TO A CLAIM OR IN 23 24 LITIGATION. 25 20 1007. A PBM SHALL DISPENSE A SUBSTITUTE PRESCRIPTION DRUG FOR A 26 (A)27 PRESCRIBED DRUG ONLY TO AN ENROLLEE ACCORDING TO THE PROVISIONS OF THIS 28 SECTION. 29 (B) A PBM MAY SUBSTITUTE A LOWER-PRICED GENERIC AND 30 THERAPEUTICALLY EOUIVALENT DRUG FOR A HIGHER PRICED PRESCRIBED DRUG. A PBM MAY SUBSTITUTE A HIGHER-PRICED PRESCRIBED DRUG FOR 31 (\mathbf{C}) (1)32 A LOWER-PRICED GENERIC DRUG ONLY FOR MEDICAL REASONS THAT BENEFIT THE 33 ENROLLEE AND THE COVERED ENTITY. IF A SUBSTITUTION IS BEING MADE UNDER PARAGRAPH (1) OF THIS 34 (2)

35 SUBSECTION, A PBM SHALL:

_		•		DISCLOSE TO THE ENROLLEE AND THE COVERED ENTITY THE ND ANY BENEFIT OR PAYMENT DIRECTLY OR INDIRECTLY AS A RESULT OF THE SUBSTITUTION; AND
-	PRESCRIBI REPRESEN			OBTAIN THE WRITTEN APPROVAL OF THE ENROLLEE'S OFESSIONAL OR THE ENROLLEE'S AUTHORIZED
		R PAYN	IENT RI	LL TRANSFER IN FULL TO THE COVERED ENTITY ANY ECEIVED IN ANY FORM BY THE PBM AS A RESULT OF A IN A STITUTION UNDER SUBSECTION (C) OF THIS SECTION.
10	20-1008.			
13 14	CERTAIN	RIPTION PRESCR	HDRUG!	DERIVES ANY PAYMENT OR BENEFIT FOR THE DISPENSING S WITHIN THE STATE BASED ON VOLUME OF SALES FOR DRUGS OR CLASSES OR BRANDS OF DRUGS WITHIN THE PAYMENT OR BENEFIT ON IN FULL TO THE COVERED
	AND ARR/	NGEM	ENTS FO	DISCLOSE TO THE COVERED ENTITY ALL FINANCIAL TERMS OR REMUNERATION OF ANY KIND THAT APPLY BETWEEN CRIPTION DRUG MANUFACTURER OR LABELER, INCLUDING:
19		(1)	FORM	ULARY MANAGEMENT AND DRUG SWITCH PROGRAMS;
20		(2)	EDUC/	ATIONAL SUPPORT;
21 22	CHARGED	(3) BY RET		IS PROCESSING AND PHARMACY NETWORK FEES THAT ARE ARMACIES; AND
23		(4)	DATA	SALES FEES.
24	20-1009.			
25 26				Y ASSESS A CIVIL PENALTY, NOT EXCEEDING \$10,000, /HO VIOLATES THIS SUBTITLE.
27	<u>(a)</u>	There is	s a Task l	Force to Study Pharmacy Benefits Management.
28	<u>(b)</u>	The Tas	sk Force	consists of the following members:
29 30		<u>(1)</u> n, appoint		mbers of the Senate of Maryland, one of whom shall serve as e President of the Senate;
31 32	<u>co-chairmar</u>	<u>(2)</u> 1, appoint		mbers of the House of Delegates, one of whom shall serve as e Speaker of the House;
33 34	designee;	<u>(3)</u>	the Sec	retary of Health and Mental Hygiene, or the Secretary's

9				HOUSE BILL 397	
1		<u>(4)</u>	the Insurance Commissioner, or the Commissioner's designee;		
2 3	designee; and	<u>(5)</u> d	the Secretary of Budget and Management, or the Secretary's		
4 5	Mental Hygi	<u>(6)</u> ene:	the follow	wing members, appointed by the Secretary of Health and	
6			<u>(i)</u>	three representatives of pharmacy benefits managers;	
7			<u>(ii)</u>	two representatives of retail pharmacies;	
8			<u>(iii)</u>	a licensed pharmacist;	
9			<u>(iv)</u>	an authorized prescriber; and	
10			<u>(v)</u>	a representative of health insurance carriers.	
11 12	(c) Task Force.	<u>The Der</u>	oartment o	of Health and Mental Hygiene shall provide staff for the	
13	<u>(d)</u>	A memb	er of the '	Task Force:	
14		<u>(1)</u>	may not	receive compensation; but	
15 16		(2) lations.	is entitled	d to reimbursement for expenses under the Standard State	
17 18	(e) including:	<u>The Tas</u>	k Force sh	nall study regulation of pharmacy benefits managers,	
19 20	manager;	<u>(1)</u>	the entiti	es included under the definition of pharmacy benefits	
21		<u>(2)</u>	<u>a State re</u>	egistration or certification process:	
22 23	a covered en	<u>(3)</u> ntity;	the fiduc	iary relationship between a pharmacy benefit manager and	
			view agent	isions of the Insurance Article, including provisions ts, that could potentially conflict with regulation of	
				cial and utilization information a pharmacy benefits provide to a covered entity and the proprietary nature	
30 31	prescription	<u>(6)</u> drug for		y of a pharmacy benefits manager to substitute another prescribed.	

31 prescription drug for the drug prescribed;

9

1 (7)whether a pharmacy benefits manager should be required to transfer 2 to a covered entity any benefit or payment received by the pharmacy benefits 3 manager as a result of a prescription drug substitution; 4 whether a pharmacy benefits manager should be required to disclose (8) 5 to a covered entity the business relationships and financial terms and arrangements 6 for remuneration that apply between the pharmacy benefits manager and a prescription drug manufacturer, mail order pharmacy, or labeler; 7 8 whether a pharmacy benefits manager should be required to allow (9) 9 into its pharmacy network any retail pharmacy that agrees to match the prices 10 offered by a mail order pharmacy; and 11 (10)the fiscal impact on the State of pharmacy benefits manager 12 regulation.

13 <u>(f)</u> The Task Force shall recommend draft legislation as a result of its study.

14 The Task Force shall report its findings and recommended draft (g)

15 legislation, in accordance with § 2-1246 of the State Government Article, to the

16 Senate Finance Committee and House Health and Government Operations

17 Committee on or before December 1, 2004.

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

19 October 1 June 1, 2004.

10

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