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By: **Delegates Rudolph, Goldwater, Elliott, and Bromwell** Introduced and read first time: February 11, 2005 Assigned to: Health and Government Operations

A BILL ENTITLED

1 AN ACT concerning

Pharmacy Benefit Managers Regulation Act of 2005

3 FOR the purpose of prohibiting a pharmacy benefit manager ("PBM") from 4 establishing the amount of a certain reimbursement on a certain basis; 5 prohibiting a PBM from imposing a certain copayment, deductible, limit on quantity, or other condition, under certain circumstances; requiring an 6 insurance policy or contract or a PBM to allow an insured or certificate holder to 7 8 obtain pharmaceutical benefits from the pharmacy or pharmacist of the insured 9 or certificate holder's choice, within any pharmacy network; requiring a PBM that provides pharmacy services to hold a pharmacy permit issued by the State 10 Board of Pharmacy; requiring a PBM to require employees or contractors to be 11 licensed pharmacists under certain circumstances; requiring a PBM to hold a 12 13 certificate of authority issued by the Maryland Insurance Commissioner; 14 establishing requirements for a certificate application and for issuing or renewing a certificate of authority; requiring the Commissioner to provide a 15 certain notice, if the Commissioner denies a certificate of authority; providing 16 17 that a certificate of authority authorizes a PBM to operate in and provide 18 services to residents of the State; providing for the expiration of a certificate of 19 authority; providing that a certificate of authority is not transferable; requiring 20 the Commissioner to keep certain information confidential; requiring the 21 Commissioner to provide certain information to the State Board of Pharmacy; 22 requiring the State Board of Pharmacy to keep certain information confidential; 23 requiring a PBM to provide enrollees certain cards or other technology and a certain telephone number; requiring a PBM to disclose and provide to a covered 24 25 entity certain information under certain circumstances; prohibiting a covered entity from disclosing certain confidential information; providing for certain 26 27 exceptions; prohibiting a PBM from substituting one prescription drug for another except under certain circumstances; requiring a certain pharmacist to 28 29 make a request for a substitution; requiring a PBM to allow an enrollee to 30 obtain covered pharmacy services from the pharmacy or pharmacist of the 31 enrollee's choice; prohibiting a PBM from taking certain actions limiting an 32 enrollee's use of pharmacy services; requiring the Commissioner and the State 33 Board of Pharmacy to create a Pharmacy Benefit Manager Appeals Board; 34 providing for the membership, duties, and confidentiality of the Appeals Board; 35 requiring a PBM to enter into written contracts with pharmacy providers;

- 1 establishing requirements for the written contracts; prohibiting a PBM from
- 2 taking certain actions; requiring the Commissioner to adopt certain regulations
- 3 on or before a certain date; requiring the Commissioner and the State Board of
- 4 Pharmacy to enforce certain provisions of law; authorizing the Commissioner to
- 5 take certain actions against a PBM under certain circumstances; authorizing
- 6 the Commissioner or the State Board of Pharmacy to assess a certain civil
- 7 penalty; authorizing the Commissioner to permit the continued operation of a
- 8 PBM for a certain period of time under certain circumstances; providing for a
- 9 certain hearing and a certain appeal; defining certain terms; and generally
- 10 relating to regulation of pharmacy benefit managers.

11 BY repealing and reenacting, with amendments,

- 12 Article Insurance
- 13 Section 15-805
- 14 Annotated Code of Maryland
- 15 (2002 Replacement Volume and 2004 Supplement)
- 16 BY adding to
- 17 Article Insurance
- 18 Section 15-1701 through 15-1717, inclusive, to be under the new subtitle
- 19 "Subtitle 17. Pharmacy Benefit Managers"
- 20 Annotated Code of Maryland
- 21 (2002 Replacement Volume and 2004 Supplement)

22 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF

- 23 MARYLAND, That the Laws of Maryland read as follows:
- 24

Article - Insurance

25 15-805.

26 (a) (1) In this section the following words have the meanings indicated.

27 (2) "Authorized prescriber" means a licensed dentist, licensed physician,
28 or licensed podiatrist who is authorized under the Health Occupations Article to
29 prescribe a pharmaceutical product.

2) presente a pharmaceutear product.

30 (3) "Pharmaceutical product" means a drug or medicine that may be31 prescribed by an authorized prescriber.

32 (4) "PHARMACY BENEFIT MANAGER" OR "PBM" HAS THE MEANING 33 STATED IN § 15-1701 OF THIS TITLE.

34 (b) This section does not apply to a policy or contract that is issued to an 35 employer under a collective bargaining agreement.

36 (c) (1) This subsection applies to:

1 **(I)** each policy or contract that is issued or delivered in the State to 2 an employer or individual by an insurer or nonprofit health service plan and that 3 provides group or individual hospital, medical, or surgical benefits; AND EACH PBM THAT PROVIDES SERVICES, INCLUDING SERVICES 4 (II) 5 PROVIDED AS AN AGENT OR CONTRACTOR, UNDER A POLICY OR CONTRACT UNDER 6 ITEM (I) OF THIS PARAGRAPH. 7 A policy, [or] contract, OR PBM subject to this subsection that (2)8 provides reimbursement for a pharmaceutical product prescribed by an authorized 9 prescriber may not establish the amount of reimbursement to the insured or the 10 insured's beneficiary, including copayments and deductibles, based on the identity, 11 practicing specialty, or occupation of the authorized prescriber. 12 (d) (1)This subsection applies to: 13 each individual or group policy or contract that is issued or (I) 14 delivered in the State to an employer or individual by an insurer or nonprofit health 15 service plan and that provides benefits for pharmaceutical products; AND 16 EACH PBM THAT PROVIDES SERVICES, INCLUDING SERVICES (II) 17 PROVIDED AS AN AGENT OR CONTRACTOR, UNDER A POLICY OR CONTRACT UNDER 18 ITEM (I) OF THIS PARAGRAPH. 19 (2)A policy, [or] contract, OR PBM subject to this subsection may not 20 impose a copayment, deductible, LIMIT ON QUANTITY, or other condition on an 21 insured or certificate holder who uses the services of a community pharmacy that is 22 not imposed when the insured or certificate holder uses the services of a mail order 23 pharmacy, if the benefits are provided under the same program, policy, or contract. 24 (E) (1)THIS SUBSECTION APPLIES TO: 25 EACH INDIVIDUAL OR GROUP POLICY OR CONTRACT THAT IS (\mathbf{I}) 26 ISSUED OR DELIVERED IN THE STATE TO AN EMPLOYER OR INDIVIDUAL BY AN 27 INSURER AND THAT PROVIDES BENEFITS FOR PHARMACEUTICAL PRODUCTS; AND

28 (II) EACH PBM THAT PROVIDES SERVICES, INCLUDING SERVICES
29 PROVIDED AS AN AGENT OR CONTRACTOR, UNDER A POLICY OR CONTRACT UNDER
30 ITEM (I) OF THIS PARAGRAPH.

(2) A POLICY, CONTRACT OR PBM SUBJECT TO THIS SUBSECTION SHALL
 ALLOW AN INSURED OR CERTIFICATE HOLDER TO SELECT THE PHARMACY OR
 PHARMACIST OF THE INSURED OR CERTIFICATE HOLDER'S CHOICE FOR
 PHARMACEUTICAL BENEFITS, WITHIN ANY PHARMACY NETWORK ESTABLISHED
 UNDER OR BY THE POLICY, CONTRACT, OR PBM.

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SUBTITLE 17. PHARMACY BENEFIT MANAGERS.

2 15-1701.

3 (A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS 4 INDICATED.

(B) "CLAIMS PROCESSING SERVICES" MEANS ADMINISTRATIVE SERVICES
PERFORMED IN CONNECTION WITH THE PROCESSING AND ADJUDICATION OF A
CLAIM FOR PRESCRIPTION DRUG OR DEVICE BENEFITS, INCLUDING MAKING
PAYMENTS TO PHARMACIES.

9 (C) (1) "COVERED ENTITY" MEANS AN INSURER, A NONPROFIT HEALTH
10 SERVICE PLAN, A HEALTH MAINTENANCE ORGANIZATION, A MANAGED CARE
11 ORGANIZATION AS DEFINED IN TITLE 15, SUBTITLE 1 OF THE HEALTH - GENERAL
12 ARTICLE, THE STATE AS A PROVIDER OF HEALTH CARE COVERAGE TO ITS
13 EMPLOYEES AND RETIREES, AN EMPLOYER, A LABOR UNION, OR ANY OTHER PERSON
14 THAT OFFERS HEALTH CARE COVERAGE THAT INCLUDES PRESCRIPTION DRUG AND
15 DEVICE BENEFITS TO ENROLLEES.

16 (2) "COVERED ENTITY" DOES NOT INCLUDE A PERSON THAT ONLY 17 OFFERS POLICIES OR CONTRACTS FOR:

- 18 (I) ACCIDENTAL INJURY;
- 19 (II) SPECIFIED DISEASES;
- 20 (III) HOSPITAL INDEMNITY;
- 21 (IV) DISABILITY INCOME;
- 22 (V) LONG-TERM CARE; OR
- 23 (VI) OTHER LIMITED BENEFITS.

(D) "ENROLLEE" MEANS A MEMBER, PARTICIPANT, CONTRACT HOLDER,
25 POLICYHOLDER, OR BENEFICIARY OF A COVERED ENTITY.

26 (E) "EXTRAPOLATION AUDIT" MEANS AN AUDIT OF A SAMPLE OF
27 PRESCRIPTION BENEFIT CLAIMS SUBMITTED BY A PHARMACY TO A PBM OR ITS
28 DESIGNATED CONTRACTOR OR AGENT THAT IS USED TO ESTIMATE AUDIT RESULTS
29 FOR A LARGER BATCH OR GROUP OF CLAIMS.

30 (F) "OTHER PRESCRIPTION DRUG OR DEVICE SERVICES" MEANS SERVICES
31 OTHER THAN PHARMACY OR CLAIMS PROCESSING SERVICES PROVIDED DIRECTLY
32 OR INDIRECTLY BY A PBM, WHETHER IN CONNECTION WITH OR SEPARATE FROM
33 CLAIMS PROCESSING, INCLUDING:

34 (1) NEGOTIATING REBATES, DISCOUNTS, OR OTHER FINANCIAL
 35 INCENTIVES AND ARRANGEMENTS WITH DRUG COMPANIES;

(2) RECEIVING, DISBURSING, OR DISTRIBUTING REBATES;

2 (3) MANAGING OR PARTICIPATING IN INCENTIVE PROGRAMS OR 3 ARRANGEMENTS FOR PRESCRIPTION BENEFITS;

4 (4) NEGOTIATING OR ENTERING INTO CONTRACTUAL ARRANGEMENTS 5 WITH PHARMACISTS OR PHARMACIES;

6 (5) DEVELOPING FORMULARIES;

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7 (6) DESIGNING, DEVELOPING, OR ARRANGING FOR PRESCRIPTION
8 BENEFIT PROGRAMS OR NETWORKS; OR

9 (7) ENGAGING IN OTHER SERVICES FOR THE PROVISION OR PAYMENT 10 OF PRESCRIPTION BENEFITS.

11 (G) "PHARMACY BENEFIT MANAGEMENT" MEANS:

12 (1) CLAIMS PROCESSING SERVICES OR OTHER PRESCRIPTION DRUG OR 13 DEVICE SERVICES; OR

14 (2) PHARMACY SERVICES.

15 (H) "PHARMACY BENEFIT MANAGER" OR "PBM" MEANS A PERSON THAT
16 PERFORMS PHARMACY BENEFITS MANAGEMENT IN A CONTRACTUAL OR
17 EMPLOYMENT RELATIONSHIP FOR A COVERED ENTITY.

18 (I) "PHARMACY PROVIDER" MEANS A PHARMACY OR PHARMACIST THAT19 CONTRACTS WITH A PBM TO PROVIDE PHARMACY SERVICES.

20 (J) "PHARMACY SERVICES" MEANS:

- 21 (1) DISPENSING OF PRESCRIPTION DRUGS OR DEVICES BY A PHARMACY;
- 22 (2) DISEASE STATE MANAGEMENT;
- 23 (3) DISEASE COMPLIANCE MANAGEMENT;
- 24 (4) DRUG COMPLIANCE PROGRAMS AND MANAGEMENT;
- 25 (5) DRUG INTERACTION MANAGEMENT;
- 26 (6) DRUG UTILIZATION MANAGEMENT;
- 27 (7) FORMULARY MANAGEMENT INTERVENTION;
- 28 (8) GENERIC ALTERNATIVE PROGRAM MANAGEMENT;
- 29 (9) DRUG THERAPY DATA ANALYSIS;
- 30 (10) DRUG UTILIZATION REVIEW SERVICES;

- 1 (11) PROVIDER PROFILING AND OUTCOMES ASSESSMENT;
- 2 (12) REFILL REMINDER PROGRAMS;
- 3 (13) THERAPY GUIDELINES MANAGEMENT;
- 4 (14) STEP THERAPY PROTOCOL MANAGEMENT;
- 5 (15) COLLABORATIVE PRACTICE;
- 6 (16) WELLNESS MANAGEMENT; OR
- 7 (17) OTHER PHARMACY CLINICAL SERVICES.

8 15-1702.

9 (A) A PBM THAT PROVIDES PHARMACY SERVICES DIRECTLY OR INDIRECTLY 10 TO RESIDENTS OF THE STATE SHALL HOLD A PHARMACY PERMIT ISSUED BY THE 11 STATE BOARD OF PHARMACY.

(B) A PBM THAT OPERATES IN OR PROVIDES SERVICES TO RESIDENTS OF THE
STATE SHALL REQUIRE EACH EMPLOYEE OR CONTRACTOR TO BE A LICENSED
PHARMACIST IF THE EMPLOYEE OR CONTRACTOR PROVIDES PHARMACY SERVICES
OR OTHER PRESCRIPTION DRUG OR DEVICE SERVICES FOR OR ON BEHALF OF THE
PBM.

17 15-1703.

18 (A) ON OR BEFORE JULY 1, 2006, A PBM THAT OPERATES IN OR PROVIDES
19 SERVICES TO RESIDENTS OF THE STATE SHALL HOLD A CERTIFICATE OF AUTHORITY
20 ISSUED BY THE COMMISSIONER.

21 (B) TO APPLY FOR A CERTIFICATE OF AUTHORITY, AN APPLICANT SHALL:

(1) SUBMIT AN APPLICATION TO THE COMMISSIONER ON THE FORMAND IN THE MANNER THE COMMISSIONER REQUIRES; AND

24(2)PAY TO THE COMMISSIONER THE APPLICATION FEE SET BY THE25COMMISSIONER.

26 (C) THE COMMISSIONER SHALL ISSUE A CERTIFICATE OF AUTHORITY TO ANY
27 APPLICANT THAT MEETS THE REQUIREMENTS OF THIS SUBTITLE.

(D) THE COMMISSIONER SHALL REQUIRE A PBM, AS A CONDITION OF ISSUING29 OR RENEWING A CERTIFICATE OF AUTHORITY:

30 (1) TO OBTAIN A PAYMENT AND PERFORMANCE BOND:

31(I)IN AN AMOUNT SUFFICIENT TO COVER THE PROVISION OF32CLAIMS PROCESSING AND OTHER PRESCRIPTION DRUG OR DEVICE SERVICES UNDER

1 THE CONTRACTS THE PBM HOLDS WITH COVERED ENTITIES AND PHARMACY 2 PROVIDERS; AND

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(II) USING THE FORM DEVELOPED BY THE COMMISSIONER; AND

4 (2) TO PROVIDE COVERED ENTITIES AND PHARMACY PROVIDERS WITH
5 COPIES OF THE CURRENT PERFORMANCE BOND APPLICABLE TO THAT COVERED
6 ENTITY OR PHARMACY PROVIDER AT THE TIME OF CONTRACTING.

7 (E) IF THE COMMISSIONER DENIES A CERTIFICATE OF AUTHORITY TO AN
8 APPLICANT, THE COMMISSIONER SHALL GIVE THE APPLICANT WRITTEN NOTICE OF
9 THE DECISION AND THE REASONS FOR THE DENIAL.

10 (F) A CERTIFICATE OF AUTHORITY AUTHORIZES A PBM TO OPERATE IN AND 11 PROVIDE SERVICES TO RESIDENTS OF THE STATE.

12 (G) A CERTIFICATE OF AUTHORITY EXPIRES ON THE JUNE 30 AFTER ITS
13 EFFECTIVE DATE, UNLESS THE CERTIFICATE OF AUTHORITY IS RENEWED FOR A
14 1-YEAR TERM, IN ACCORDANCE WITH PROCEDURES AND FOR A RENEWAL FEE
15 ESTABLISHED BY THE COMMISSIONER.

16 (H) IF A CERTIFICATE OF AUTHORITY IS NOT RENEWED, IT SHALL EXPIRE ON 17 THE LAST DAY OF ITS TERM.

18 (I) A CERTIFICATE OF AUTHORITY IS NOT TRANSFERABLE.

19 15-1704.

20 (A) (1) EXCEPT AS PROVIDED IN SUBSECTION (B) OF THIS SECTION, THE
21 COMMISSIONER SHALL KEEP CONFIDENTIAL ANY INFORMATION DISCLOSED TO OR
22 OTHERWISE OBTAINED BY THE COMMISSIONER THAT RELATES TO A TRADE SECRET
23 UNDER § 1905 OF TITLE 18 OF THE U.S. CODE OR APPLICABLE STATE LAW.

24 (2) THE COMMISSIONER SHALL PROVIDE THE PBM WITH AN
25 OPPORTUNITY TO IDENTIFY ANY INFORMATION THE PBM CONSIDERS A TRADE
26 SECRET.

27 (B) (1) ON REQUEST, THE COMMISSIONER SHALL PROVIDE THE STATE 28 BOARD OF PHARMACY WITH:

29(I)COPIES OF APPLICATIONS, CORRESPONDENCE, AND ANY30OTHER DOCUMENTS PROVIDED BY THE PBM TO THE COMMISSIONER; AND

31(II)COPIES OF DOCUMENTS OR INFORMATION PROVIDED BY THE32COMMISSIONER TO THE PBM.

(2) THE STATE BOARD OF PHARMACY SHALL KEEP CONFIDENTIAL ANY
INFORMATION DISCLOSED TO OR OTHERWISE OBTAINED BY THE BOARD THAT
RELATES TO A TRADE SECRET UNDER § 1905 OF TITLE 18 OF THE U.S. CODE OR
APPLICABLE STATE LAW.

1 15-1705.

A PBM SHALL PROVIDE TO ENROLLEES OF COVERED ENTITIES PRESCRIPTION
DRUG OR DEVICE BENEFIT CARDS OR OTHER TECHNOLOGY THAT MEETS THE
STANDARDS OF THE NATIONAL COUNCIL FOR PRESCRIPTION DRUG PROGRAMS
PHARMACY ID CARD IMPLEMENTATION GUIDE OR ANY REPLACEMENT GUIDE.

6 15-1706.

7 A PBM SHALL PROVIDE A TOLL-FREE TELEPHONE NUMBER THAT OPERATES 78 DAYS A WEEK FROM 9:00 A.M. UNTIL 9:00 P.M.:

9 (1) FOR PHARMACY PROVIDERS TO CALL WITH INQUIRIES ABOUT 10 CLAIMS; AND

11(2)FOR ENROLLEES OF COVERED ENTITIES TO CALL WITH INQUIRIES12ABOUT BENEFITS.

13 15-1707.

14 (A) A PBM THAT DERIVES ANY PAYMENT OR BENEFIT FROM A DRUG
15 MANUFACTURER OR DISTRIBUTOR FOR PROVIDING PHARMACY BENEFITS
16 MANAGEMENT BASED ON VOLUME OR ANY OTHER MEASURE OF SALES OR
17 PRESCRIBING OR DISPENSING OF CERTAIN PRESCRIPTION DRUGS OR CLASSES OR
18 BRANDS OF DRUGS SHALL DISCLOSE TO A COVERED ENTITY THE AMOUNT OF
19 PAYMENTS AND BENEFITS:

20 (1) THE PBM RECEIVED; AND

21 (2) THE PBM RETAINED AFTER MAKING ANY DISTRIBUTION TO THE 22 COVERED ENTITY.

(B) (1) A PBM SHALL PROVIDE TO A COVERED ENTITY ALL FINANCIAL AND
UTILIZATION INFORMATION REQUESTED BY THE COVERED ENTITY RELATING TO
THE PROVISION OF BENEFITS TO THE ENROLLEES OF THE COVERED ENTITY.

26(2)A PBM MAY DESIGNATE AS CONFIDENTIAL INFORMATION PROVIDED27UNDER THIS SUBSECTION IN THE PBM'S CONTRACT WITH THE COVERED ENTITY.

(3) (I) EXCEPT AS PROVIDED IN SUBPARAGRAPH (II) OF THIS
PARAGRAPH, A COVERED ENTITY MAY NOT DISCLOSE INFORMATION THE PBM
DESIGNATES BY CONTRACT AS CONFIDENTIAL WITHOUT THE CONSENT OF THE PBM.

31(II)A COVERED ENTITY MAY DISCLOSE CONFIDENTIAL32 INFORMATION:

331.IN A COURT FILING UNDER ANY CIVIL PROCEEDING OR34STATE PROSECUTION FOR VIOLATION OF THIS SUBTITLE FOR GOOD CAUSE;

352.WHEN AUTHORIZED BY ANY OTHER STATE OR FEDERAL36 LAW; OR

WHEN ORDERED BY A COURT OF THIS STATE FOR GOOD

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2 CAUSE.

3 15-1708.

4 (A) A PBM MAY NOT SUBSTITUTE ANOTHER PRESCRIPTION DRUG FOR THE 5 DRUG ORIGINALLY PRESCRIBED UNLESS:

6 (1) THE SUBSTITUTION IS MADE FOR MEDICAL REASONS THAT BENEFIT 7 THE ENROLLEE; OR

8 (2) THE SUBSTITUTION RESULTS IN FINANCIAL SAVINGS AND BENEFITS 9 TO THE COVERED ENTITY.

10 (B) IF A SUBSTITUTION IS MADE UNDER THIS SECTION, THE PBM SHALL
11 DISCLOSE TO THE COVERED ENTITY ANY BENEFIT OR PAYMENT RECEIVED IN ANY
12 FORM BY THE PBM FROM A DRUG MANUFACTURER OR OTHER PERSON WITH REGARD
13 TO THE SUBSTITUTION.

14 (C) A PHARMACIST FROM THE PHARMACY WHERE THE ORIGINAL
15 PRESCRIPTION IS ON FILE SHALL MAKE THE REQUEST TO THE AUTHORIZED
16 PRESCRIBER FOR THE SUBSTITUTION.

17 15-1709.

18 A PBM:

19(1)SHALL ALLOW AN ENROLLEE TO OBTAIN COVERED PHARMACY20SERVICES FROM THE PHARMACY OR PHARMACIST OF THE ENROLLEE'S CHOICE21WITHIN THE PBM'S PHARMACY NETWORK; AND

22 (2) MAY NOT:

23 (I) REQUIRE AN ENROLLEE TO OBTAIN PHARMACY SERVICES 24 FROM A MAIL-ORDER PHARMACY;

25 (II) USE ANY FINANCIAL OR OTHER DISINCENTIVES, PENALTIES,
26 OR OTHER MEANS TO INFLUENCE, COERCE, OR STEER ENROLLEES AWAY FROM A
27 RETAIL PHARMACY; OR

(III) LIMIT THE QUANTITY OF DRUGS THAT AN ENROLLEE MAY
OBTAIN AT ANY ONE TIME FROM ANY TYPE OF PHARMACY PROVIDER UNLESS THE
LIMIT IS APPLIED UNIFORMLY TO ALL PHARMACY PROVIDERS THAT ARE WITHIN THE
PHARMACY NETWORK, UNDER CONTRACT, OR OTHERWISE AUTHORIZED TO PROVIDE
PHARMACY SERVICES TO ENROLLEES.

33 15-1710.

34 (A) IN THIS SECTION, "PBM APPEALS BOARD" MEANS THE PHARMACY35 BENEFIT MANAGER APPEALS BOARD.

10 UNOFFICIAL COPY O	F HOUSE BILL 1058
1 (B) THE COMMISSIONER AND THE STATE BOARD OF PHARMACY SHALL 2 CREATE A PHARMACY BENEFIT MANAGER APPEALS BOARD.	
3 (C) (1) THE PBM APPEALS BO	ARD SHALL CONSIST OF:
4 (I) TWO MEMBERS	S APPOINTED BY THE COMMISSIONER;
5 (II) TWO MEMBERS 6 PHARMACY; AND	S APPOINTED BY THE STATE BOARD OF
7 (III) ONE CONSUME 8 COMMISSIONER AND THE STATE BOARD	R MEMBER APPOINTED JOINTLY BY THE OF PHARMACY.
9 (2) (I) THE TWO MEM 10 BE PHARMACISTS HOLDING A PHARMAC 11 STATE.	BERS APPOINTED BY THE COMMISSIONER SHALL IST LICENSE IN GOOD STANDING IN THE
 12 (II) THE TWO MEM 13 PHARMACY SHALL BE COMMUNITY PHA 14 ASSOCIATED WITH A PBM AND HOLDING 15 STANDING IN THE STATE. 	
16 (III) THE CONSUME	R MEMBER MAY NOT:
171.HAVE A CURRENT OR PREVIOUS ASSOCIATION OR18EMPLOYMENT WITH A PBM; OR	
19 2. BE A PH	IARMACIST.
20 (3) A MEMBER SHALL BE	APPOINTED FOR A PERIOD OF 2 YEARS.
21 (D) THE PBM APPEALS BOARD SHALL:	
22 (1) HEAR DISPUTES BETW 23 RELATING TO:	EEN PBMS AND PHARMACY PROVIDERS
24 (I) CONTRACTS;	
25 (II) AUDIT PROCEE	DURES, INCLUDING EXTRAPOLATION AUDITS;
26 (III) CLAIMS ADJUE	VICATION; AND
27 (IV) PAYMENT OF C	CLAIMS TO PHARMACY PROVIDERS; AND
28(2)ISSUE RECOMMENDATIONS TO THE COMMISSIONER OR THE STATE29BOARD OF PHARMACY, AS NECESSARY AND APPROPRIATE, FOR FINAL ACTION.	
30 (E) EXCEPT FOR RECOMMENDATIONS TO THE COMMISSIONER OR THE STATE 31 BOARD OF PHARMACY, ALL DISCUSSIONS, PROCEEDINGS, DOCUMENTS, REPORTS, 32 DETERMINATIONS, DECISIONS, FINDINGS, OR COMMUNICATIONS PREPARED BY,	

32 DETERMINATIONS, DECISIONS, FINDINGS, OR COMMUNICATIONS PREPARED BY,33 RECEIVED BY, OR CREATED BY THE PBM APPEALS BOARD:

1 (1) SHALL BE CONFIDENTIAL, PRIVILEGED, AND NOT FOR PUBLIC 2 DISCLOSURE; AND

3 (2) MAY NOT BE DISCOVERABLE OR ADMISSIBLE AS EVIDENCE IN ANY
4 CIVIL ADMINISTRATIVE PROCEEDING OR SUBJECT TO FEDERAL OR STATE FREEDOM
5 OF INFORMATION LAWS.

6 15-1711.

7 (A) BEFORE A PBM MAY PROVIDE PHARMACY BENEFIT MANAGEMENT
8 SERVICES IN THE STATE, THE PBM SHALL ENTER INTO WRITTEN CONTRACTS WITH
9 PHARMACY PROVIDERS.

10 (B) THE WRITTEN CONTRACT SHALL REQUIRE PBMS TO:

(1) PROVIDE FULL DISCLOSURE TO PHARMACY PROVIDERS BEFORE
 IMPLEMENTATION OF THE CONTRACT, NETWORK, OR PROGRAM OF THE TERMS,
 CONDITIONS, FEES, BENEFIT DESIGNS, PROCESS, AND PROCEDURES FOR ACCESSING
 THE PBM BENEFIT AND HANDLING DISPUTES;

(2) PROVIDE AT LEAST 30 DAYS WRITTEN NOTICE TO ENROLLEES AND
 PHARMACY PROVIDERS OF BENEFIT CHANGES, INCLUDING ADDITIONS OR
 DELETIONS TO COVERED PRESCRIPTION MEDICATIONS, WITH THE EXCEPTION OF
 NEW MEDICATIONS APPROVED BY THE U.S. FOOD AND DRUG ADMINISTRATION;

19(3)PROVIDE PHARMACISTS AND PHARMACIES THE OPTION OF USING20THE PBM APPEALS BOARD TO RESOLVE DISPUTES;

(4) PROVIDE OR REQUIRE CONTRACTORS OR AGENTS OF THE PBM TO
 PROVIDE ENROLLEES WITH PRESCRIPTION DRUG OR DEVICE BENEFIT CARDS OR
 OTHER TECHNOLOGY THAT COMPLIES WITH THE NATIONAL COUNCIL FOR
 PRESCRIPTION DRUG PROGRAMS PHARMACY ID CARD IMPLEMENTATION GUIDE OR
 ITS REPLACEMENT GUIDE;

26 (5) STIPULATE THAT PHARMACY PROVIDERS WILL NOT BE REQUIRED TO
27 AGREE TO EXTRAPOLATION AUDITS AS A CONDITION OF PARTICIPATION IN THE
28 CONTRACT, NETWORK, OR PROGRAM.

29 15-1712.

30 A PBM MAY NOT ITSELF OR THROUGH THE USE OF A CONTRACTOR OR AGENT:

31 (1) MAKE ANY ORAL OR WRITTEN MISREPRESENTATION WITH REGARD
32 TO THE TERMS OR EFFECTS OF A CONTRACT WITH ANY PHARMACY PROVIDER TO
33 ANY:

34 (I) PHARMACY PROVIDER OR PHARMACIST;

35 (II) AGENT, REPRESENTATIVE, OR EMPLOYEE OF A PHARMACY
 36 PROVIDER OR PHARMACIST; OR

1 (III) ENROLLEE;

2 (2) INTERVENE IN THE DELIVERY OR TRANSMISSION OF
3 PRESCRIPTIONS FROM THE PRESCRIBER TO THE PHARMACY FOR THE PURPOSE OF:

4 (I) INFLUENCING THE PRESCRIBER'S CHOICE OF THERAPY OR 5 PHARMACY PROVIDER; OR

6 (II) ALTERING THE PRESCRIPTION INFORMATION, INCLUDING
7 SWITCHING OR SUBSTITUTING THE PRESCRIBED DRUG WITHOUT THE EXPRESS
8 AUTHORIZATION OF THE PRESCRIBER;

9 (3) ALTER THE PRESCRIPTION INFORMATION OR CONTENT IN AN 10 ELECTRONICALLY TRANSMITTED PRESCRIPTION, UNLESS THE ALTERATION IS 11 AUTHORIZED BY LAW;

12 (4) FAIL TO MAKE PROMPT PAYMENT OF CLAIMS OR OTHER 13 REIMBURSEMENT TO PHARMACY PROVIDERS;

14 (5) (I) ENGAGE IN OR INTERFERE WITH THE PRACTICE OF MEDICINE;

(II) INTERVENE IN THE PRACTICE OF MEDICINE BETWEEN
 PRESCRIBERS AND THEIR PATIENTS, INCLUDING THE PRESCRIBING OF DRUGS AND
 DEVICES; OR

18 (III) INTERFERE WITH OR INTERVENE IN THE RELATIONSHIP 19 BETWEEN A PATIENT AND A PHARMACY;

(6) CHANGE, AMEND, REVISE, ADD, REMOVE, OR MODIFY ANY MATERIAL
 TERMS, PROVISIONS, OR CONDITIONS OF ANY CONTRACT WITH A PHARMACY
 PROVIDER AND ANY ACCOMPANYING PHARMACY SERVICES MANUALS OR
 DOCUMENTS DURING THE TERM OF THE PHARMACY PROVIDER CONTRACT WITHOUT
 THE EXPRESS WRITTEN CONSENT AND AGREEMENT OF THE PHARMACY PROVIDER;

(7) WITHHOLD, RECOUP, OR ATTEMPT TO RECOUP ANY FUNDS DUE TO A
PHARMACY PROVIDER FROM AN AUDIT THROUGH A SETOFF AGAINST FUTURE SUMS
DUE AND OWING TO A PHARMACY PROVIDER;

(8) RETROACTIVELY REVERSE OR DENY ACKNOWLEDGMENT OF
PARTICIPANT ELIGIBILITY, OR DENY OR ADJUST PAYMENTS AFTER ADJUDICATING
PHARMACY CLAIMS, EXCEPT FOR CIRCUMSTANCES IN WHICH THE PBM PROVIDES
EVIDENCE THAT:

32 (I) THE PAYMENT TO THE PHARMACY PROVIDER IS A DUPLICATE;

33 (II) THE CLAIM IS FRAUDULENT; OR

(III) THE PHARMACY DID NOT PROVIDE THE PRESCRIPTION
 SERVICES TO THE ENROLLEE; OR

36 (9) OTHERWISE VIOLATE ANY PROVISION OF THIS SUBTITLE.

1 15-1713.

2 ON OR BEFORE APRIL 1, 2006, THE COMMISSIONER SHALL ADOPT REGULATIONS 3 TO IMPLEMENT THE PROVISIONS OF THIS SUBTITLE.

4 15-1714.

5 (A) EXCEPT AS PROVIDED IN SUBSECTION (B) OF THIS SECTION, THE 6 COMMISSIONER SHALL ENFORCE THE PROVISIONS OF THIS SUBTITLE.

7 (B) THE STATE BOARD OF PHARMACY SHALL ENFORCE THE PROVISIONS OF 8 THIS SUBTITLE THAT RELATE TO PHARMACY SERVICES.

9 15-1715.

10 (A) THE COMMISSIONER MAY SUSPEND, REVOKE, DENY, OR RESTRICT A 11 CERTIFICATE OF AUTHORITY OF A PBM IF THE PBM:

12 (1) OPERATES IN A MANNER TO ENDANGER THE PUBLIC HEALTH OR 13 SAFETY;

14 (2) ENGAGES IN FRAUD AND ABUSE OR IS SUSPECTED OF ENGAGING IN 15 FRAUD AND ABUSE;

16 (3) VIOLATES ANY OF THE REQUIREMENTS OF THIS SUBTITLE; OR

17 (4) OTHERWISE VIOLATES ANY PROVISION OF STATE OR FEDERAL LAW
 18 OR REGULATION.

(B) IF A CERTIFICATE IS SUSPENDED, REVOKED, OR DENIED, THE
COMMISSIONER MAY PERMIT THE CONTINUED OPERATION OF THE PBM FOR A
LIMITED PERIOD, NOT TO EXCEED 60 DAYS, UNDER CONDITIONS AND RESTRICTIONS
DETERMINED BY THE COMMISSIONER TO BE NECESSARY FOR THE BENEFICIAL
INTERESTS OF ENROLLEES AND PHARMACY PROVIDERS.

24 15-1716.

IN ADDITION TO THE PENALTIES AUTHORIZED IN § 15-1715 OF THIS SUBTITLE,
THE COMMISSIONER OR THE STATE BOARD OF PHARMACY MAY ASSESS A CIVIL
PENALTY, NOT EXCEEDING \$10,000, AGAINST ANY PERSON THAT VIOLATES THIS
SUBTITLE.

29 15-1717.

30 (A) EXCEPT AS OTHERWISE PROVIDED IN THE ADMINISTRATIVE PROCEDURE
31 ACT, BEFORE THE COMMISSIONER TAKES ANY ACTION TO SUSPEND, REVOKE, OR
32 DENY A CERTIFICATE OF AUTHORITY OR ASSESS A CIVIL PENALTY, THE
33 COMMISSIONER SHALL GIVE THE PBM AN OPPORTUNITY FOR A HEARING BEFORE
34 THE COMMISSIONER.

1 (B) THE COMMISSIONER SHALL GIVE NOTICE AND HOLD THE HEARING IN 2 ACCORDANCE WITH THE ADMINISTRATIVE PROCEDURE ACT.

3 (C) A PBM FOR WHICH AN APPLICATION HAS BEEN SUSPENDED, REVOKED, OR
4 DENIED OR THAT HAS RECEIVED A CIVIL PENALTY MAY APPEAL THE ACTION AS
5 PROVIDED UNDER THE ADMINISTRATIVE PROCEDURE ACT.

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

7 October 1, 2005.