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Assigned to: Health and Government Operations

Committee Report: Favorable with amendments

House action: Adopted

Read second time: March 15, 2005

CHAPTER _____

1 AN ACT concerning

2 **Pharmacy ~~Benefit~~ Benefits Managers Regulation Act of 2005**

3 FOR the purpose of prohibiting a pharmacy ~~benefit~~ benefits manager ("~~PBM~~") from
4 establishing the amount of a certain reimbursement on a certain basis;
5 prohibiting a ~~PBM~~ pharmacy benefits manager from imposing a certain
6 copayment, deductible, limit on quantity, or other condition, under certain
7 circumstances; requiring an insurance policy or contract or a ~~PBM~~ pharmacy
8 benefits manager to allow an insured or certificate holder to obtain
9 pharmaceutical benefits from the pharmacy or pharmacist of the insured or
10 certificate holder's choice, within any pharmacy network; ~~requiring a PBM that~~
11 ~~provides pharmacy services to hold a pharmacy permit issued by the State~~
12 ~~Board of Pharmacy; requiring a PBM to require employees or contractors to be~~
13 ~~licensed pharmacists under certain circumstances; requiring a PBM to hold a~~
14 ~~certificate of authority issued by the Maryland Insurance Commissioner;~~
15 ~~establishing requirements for a certificate application and for issuing or~~
16 ~~renewing a certificate of authority; requiring the Commissioner to provide a~~
17 ~~certain notice, if the Commissioner denies a certificate of authority; providing~~
18 ~~that a certificate of authority authorizes a PBM to operate in and provide~~
19 ~~services to residents of the State; providing for the expiration of a certificate of~~
20 ~~authority; providing that a certificate of authority is not transferable; requiring~~
21 ~~the Commissioner to keep certain information confidential; requiring the~~
22 ~~Commissioner to provide certain information to the State Board of Pharmacy;~~
23 ~~requiring the State Board of Pharmacy to keep certain information confidential;~~
24 ~~requiring a PBM to provide enrollees certain cards or other technology and a~~
25 ~~certain telephone number; requiring a PBM to disclose and provide to a covered~~
26 ~~entity certain information under certain circumstances; prohibiting a covered~~

entity from disclosing certain confidential information; providing for certain exceptions; prohibiting a PBM from substituting one prescription drug for another except under certain circumstances; requiring a certain pharmacist to make a request for a substitution; requiring a PBM to allow an enrollee to obtain covered pharmacy services from the pharmacy or pharmacist of the enrollee's choice; prohibiting a PBM from taking certain actions limiting an enrollee's use of pharmacy services; requiring the Commissioner and the State Board of Pharmacy to create a Pharmacy Benefit Manager Appeals Board; providing for the membership, duties, and confidentiality of the Appeals Board; requiring a PBM to enter into written contracts with pharmacy providers; establishing requirements for the written contracts; prohibiting a PBM from taking certain actions; requiring the Commissioner to adopt certain regulations on or before a certain date; requiring the Commissioner and the State Board of Pharmacy to enforce certain provisions of law; authorizing the Commissioner to take certain actions against a PBM under certain circumstances; authorizing the Commissioner or the State Board of Pharmacy to assess a certain civil penalty; authorizing the Commissioner to permit the continued operation of a PBM for a certain period of time under certain circumstances; providing for a certain hearing and a certain appeal; exempting certain managed care organizations, insurers, nonprofit health service plans, and health maintenance organizations, and affiliates, subsidiaries, or other related entities of certain insurers, nonprofit health service plans, and health maintenance organizations from certain provisions of this Act, under certain circumstances; requiring a person to register with the Maryland Insurance Commissioner before the person acts as or represents itself as a pharmacy benefits manager in the State; requiring an applicant for registration file an application on a certain form and pay to the Commissioner a certain fee; requiring the Commissioner to register certain applicants; providing for the expiration and renewal of a registration; prohibiting a pharmacy benefits manager from taking certain actions; authorizing the Commissioner to deny a registration to an applicant or refuse to renew, suspend, or revoke a registration under certain circumstances and subject to certain hearing provisions; authorizing the Commissioner, if a registration is suspended or revoked, to permit the continued operation of a pharmacy benefits manager, for a certain period of time and under certain circumstances; requiring a pharmacy benefits manager to register as a third party administrator or a private review agent under certain circumstances; prohibiting, with a certain exception, an insurer, nonprofit health service plan, or health maintenance organization from entering into an agreement with a pharmacy benefits manager that has not registered with the Commissioner; requiring the Commissioner to conduct a certain examination in accordance with certain provisions of law; requiring a pharmacy benefits manager to maintain certain books and records for a certain period and in accordance with certain standards; requiring the Commissioner to adopt certain regulations on or before a certain date; requiring a pharmacy benefits manager to disclose in writing certain information to a prospective purchaser and a purchaser; specifying the manner in which certain disclosures must be provided; providing that a pharmacy benefits manager need not make certain disclosures unless and until the prospective purchaser or the purchaser agrees in writing to maintain

certain information as confidential; providing that certain agreements may include certain remedies and certain persons; requiring a contract executed by a pharmacy benefits manager for the provision of pharmacy benefits management services to include certain items; establishing certain requirements for members of a pharmacy and therapeutics committee; prohibiting a pharmacy benefits manager from substituting one prescription drug for the drug originally prescribed unless certain conditions are met; requiring a pharmacy benefits manager to disclose certain information to a purchaser if a drug substitution is made; requiring a pharmacy benefits manager to obtain a certain authorization to make a drug substitution and to make certain disclosures to a prescriber; providing for certain exceptions; prohibiting a pharmacy benefits manager from substituting a drug for a currently prescribed drug unless the pharmacy benefits manager provides a beneficiary or the beneficiary's representative with certain information; requiring a pharmacy benefits manager to maintain a certain toll-free telephone number; requiring a pharmacy benefits manager to enter into certain contracts with pharmacy providers under certain circumstances; specifying certain requirements of the contracts; requiring a pharmacy benefits manager to allow a beneficiary to obtain covered pharmacy services from a certain pharmacy provider and allow a certain pharmacy that can meet certain conditions to provide certain services; requiring certain disclosures to comply with certain privacy standards; providing certain penalties; altering the definition of a "nonresident pharmacy" to include a pharmacy benefits manager under certain provisions of law; requiring a nonresident pharmacy to meet certain requirements; making certain provisions of law applicable to health maintenance organizations; allowing a certain person to act as a pharmacy benefits manager without registering with the Maryland Insurance Commissioner under certain circumstances; defining certain terms; and generally relating to regulation of pharmacy ~~benefit~~ benefits managers.

29 BY adding to

Article - Health - General
Section 19-706(ddd)
Annotated Code of Maryland
(2000 Replacement Volume and 2004 Supplement)

34 BY repealing and reenacting, with amendments,

Article - Insurance
Section 15-805
Annotated Code of Maryland
(2002 Replacement Volume and 2004 Supplement)

39 BY adding to

Article - Insurance
Section 15-1701 through ~~15-1717~~ 15-1723, inclusive, to be under the new
subtitle "Subtitle 17. Pharmacy ~~Benefit~~ Benefits Managers"
Annotated Code of Maryland

1 (2002 Replacement Volume and 2004 Supplement)

2 BY repealing and reenacting, with amendments,

3 Article - Health Occupations

4 Section 12-101(k) and 12-403(e) and (f)

5 Annotated Code of Maryland

6 (2000 Replacement Volume and 2004 Supplement)

7 BY repealing and reenacting, without amendments,

8 Article - Health Occupations

9 Section 12-403(a), (b)(17), (d), and (g)

10 Annotated Code of Maryland

11 (2000 Replacement Volume and 2004 Supplement)

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

14 **Article - Health - General**

15 19-706.

16 (DDD) THE PROVISIONS OF § 15-805 AND TITLE 15, SUBTITLE 17 OF THE
17 INSURANCE ARTICLE SHALL APPLY TO HEALTH MAINTENANCE ORGANIZATIONS.

18 **Article - Insurance**

19 15-805.

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

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

24 (3) "Pharmaceutical product" means a drug or medicine that may be
25 prescribed by an authorized prescriber.

26 (4) "~~PHARMACY BENEFIT MANAGER~~" OR "~~PBM~~ BENEFITS MANAGER" HAS
27 THE MEANING STATED IN § 15-1701 OF THIS TITLE.

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

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

31 (I) each policy or contract that is issued or delivered in the State to
32 an employer or individual by an insurer or nonprofit health service plan and that
33 provides group or individual hospital, medical, or surgical benefits; AND

1 (II) EACH ~~PBM~~ PHARMACY BENEFITS MANAGER THAT PROVIDES
2 SERVICES, INCLUDING SERVICES PROVIDED AS AN AGENT OR CONTRACTOR, UNDER
3 A POLICY OR CONTRACT UNDER ITEM (I) OF THIS PARAGRAPH.

4 (2) A policy, [or] contract, OR ~~PBM~~ PHARMACY BENEFITS MANAGER
5 subject to this subsection that provides reimbursement for a pharmaceutical product
6 prescribed by an authorized prescriber may not establish the amount of
7 reimbursement to the insured or the insured's beneficiary, including copayments and
8 deductibles, based on the identity, practicing specialty, or occupation of the authorized
9 prescriber.

10 (d) (1) This subsection applies to:

11 (I) each individual or group policy or contract that is issued or
12 delivered in the State to an employer or individual by an insurer or nonprofit health
13 service plan and that provides benefits for pharmaceutical products; AND

14 (II) EACH ~~PBM~~ PHARMACY BENEFITS MANAGER THAT PROVIDES
15 SERVICES, INCLUDING SERVICES PROVIDED AS AN AGENT OR CONTRACTOR, UNDER
16 A POLICY OR CONTRACT UNDER ITEM (I) OF THIS PARAGRAPH.

17 (2) A policy, [or] contract, OR ~~PBM~~ PHARMACY BENEFITS MANAGER
18 subject to this subsection may not impose a copayment, deductible, LIMIT ON
19 QUANTITY, or other condition on an insured or certificate holder who uses the services
20 of a community pharmacy that is not imposed when the insured or certificate holder
21 uses the services of a mail order pharmacy, if the benefits are provided under the
22 same program, policy, or contract.

23 (E) (1) THIS SUBSECTION APPLIES TO:

24 (I) EACH INDIVIDUAL OR GROUP POLICY OR CONTRACT THAT IS
25 ISSUED OR DELIVERED IN THE STATE TO AN EMPLOYER OR INDIVIDUAL BY AN
26 INSURER AND THAT PROVIDES BENEFITS FOR PHARMACEUTICAL PRODUCTS; AND

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

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

SUBTITLE 17. PHARMACY ~~BENEFIT~~ BENEFITS MANAGERS.

15-1701.

(A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS 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.~~

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

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

~~(I) ACCIDENTAL INJURY;~~

~~(II) SPECIFIED DISEASES;~~

~~(III) HOSPITAL INDEMNITY;~~

~~(IV) DISABILITY INCOME;~~

~~(V) LONG-TERM CARE; OR~~

~~(VI) OTHER LIMITED BENEFITS.~~

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

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

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

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

- 1 (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;~~
- 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 THAT~~
19 ~~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.~~

12 (B) ~~A PBM THAT OPERATES IN OR PROVIDES SERVICES TO RESIDENTS OF THE~~
13 ~~STATE SHALL REQUIRE EACH EMPLOYEE OR CONTRACTOR TO BE A LICENSED~~
14 ~~PHARMACIST IF THE EMPLOYEE OR CONTRACTOR PROVIDES PHARMACY SERVICES~~
15 ~~OR OTHER PRESCRIPTION DRUG OR DEVICE SERVICES FOR OR ON BEHALF OF THE~~
16 ~~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:~~

22 (1) ~~SUBMIT AN APPLICATION TO THE COMMISSIONER ON THE FORM~~
23 ~~AND IN THE MANNER THE COMMISSIONER REQUIRES; AND~~

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

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

28 (D) ~~THE COMMISSIONER SHALL REQUIRE A PBM, AS A CONDITION OF ISSUING~~
29 ~~OR RENEWING A CERTIFICATE OF AUTHORITY:~~

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

31 (1) ~~IN AN AMOUNT SUFFICIENT TO COVER THE PROVISION OF~~
32 ~~CLAIMS PROCESSING AND OTHER PRESCRIPTION DRUG OR DEVICE SERVICES UNDER~~

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

3 ~~(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 ~~45-1704.~~

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 ANY~~
30 ~~OTHER DOCUMENTS PROVIDED BY THE PBM TO THE COMMISSIONER; AND~~

31 ~~(II) COPIES OF DOCUMENTS OR INFORMATION PROVIDED BY THE~~
32 ~~COMMISSIONER TO THE PBM.~~

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

1 ~~15-1705.~~

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

6 ~~15-1706.~~

7 ~~A PBM SHALL PROVIDE A TOLL FREE TELEPHONE NUMBER THAT OPERATES 7~~
8 ~~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 INQUIRIES~~
12 ~~ABOUT 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.~~

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

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

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

31 ~~(II) A COVERED ENTITY MAY DISCLOSE CONFIDENTIAL~~
32 ~~INFORMATION:~~

33 ~~1. IN A COURT FILING UNDER ANY CIVIL PROCEEDING OR~~
34 ~~STATE PROSECUTION FOR VIOLATION OF THIS SUBTITLE FOR GOOD CAUSE;~~

35 ~~2. WHEN AUTHORIZED BY ANY OTHER STATE OR FEDERAL~~
36 ~~LAW; OR~~

3. ~~WHEN ORDERED BY A COURT OF THIS STATE FOR GOOD~~

2 ~~CAUSE.~~

3 ~~15 1708.~~

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

6 (4) 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.

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

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

17 ~~15 1709.~~

18 ~~A PBM:~~

19 (4) ~~SHALL ALLOW AN ENROLLEE TO OBTAIN COVERED PHARMACY~~
20 ~~SERVICES FROM THE PHARMACY OR PHARMACIST OF THE ENROLLEE'S CHOICE~~
21 ~~WITHIN 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

~~(H) 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 PHARMACY
35 BENEFIT MANAGER APPEALS BOARD.

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 BOARD SHALL CONSIST OF:~~

4 ~~(I) TWO MEMBERS APPOINTED BY THE COMMISSIONER;~~

5 ~~(II) TWO MEMBERS APPOINTED BY THE STATE BOARD OF~~
6 ~~PHARMACY; AND~~

7 ~~(III) ONE CONSUMER MEMBER APPOINTED JOINTLY BY THE~~
8 ~~COMMISSIONER AND THE STATE BOARD OF PHARMACY.~~

9 ~~(2) (I) THE TWO MEMBERS APPOINTED BY THE COMMISSIONER SHALL~~
10 ~~BE PHARMACISTS HOLDING A PHARMACIST LICENSE IN GOOD STANDING IN THE~~
11 ~~STATE.~~

12 ~~(II) THE TWO MEMBERS APPOINTED BY THE STATE BOARD OF~~
13 ~~PHARMACY SHALL BE COMMUNITY PHARMACISTS NOT EMPLOYED BY OR~~
14 ~~ASSOCIATED WITH A PBM AND HOLDING A PHARMACIST LICENSE IN GOOD~~
15 ~~STANDING IN THE STATE.~~

16 ~~(III) THE CONSUMER MEMBER MAY NOT:~~

17 ~~1. HAVE A CURRENT OR PREVIOUS ASSOCIATION OR~~
18 ~~EMPLOYMENT WITH A PBM; OR~~

19 ~~2. BE A PHARMACIST.~~

20 ~~(3) A MEMBER SHALL BE APPOINTED FOR A PERIOD OF 2 YEARS.~~

21 (D) ~~THE PBM APPEALS BOARD SHALL:~~

22 ~~(1) HEAR DISPUTES BETWEEN PBMS AND PHARMACY PROVIDERS~~
23 ~~RELATING TO:~~

24 ~~(I) CONTRACTS;~~

25 ~~(II) AUDIT PROCEDURES, INCLUDING EXTRAPOLATION AUDITS;~~

26 ~~(III) CLAIMS ADJUDICATION; AND~~

27 ~~(IV) PAYMENT OF CLAIMS TO PHARMACY PROVIDERS; AND~~

28 ~~(2) ISSUE RECOMMENDATIONS TO THE COMMISSIONER OR THE STATE~~
29 ~~BOARD 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,~~
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:~~

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

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

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

21 (4) ~~PROVIDE OR REQUIRE CONTRACTORS OR AGENTS OF THE PBM TO~~
22 ~~PROVIDE ENROLLEES WITH PRESCRIPTION DRUG OR DEVICE BENEFIT CARDS OR~~
23 ~~OTHER TECHNOLOGY THAT COMPLIES WITH THE NATIONAL COUNCIL FOR~~
24 ~~PRESCRIPTION DRUG PROGRAMS PHARMACY ID CARD IMPLEMENTATION GUIDE OR~~
25 ~~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;
15 (II) INTERVENE IN THE PRACTICE OF MEDICINE BETWEEN
16 PRESCRIBERS AND THEIR PATIENTS, INCLUDING THE PRESCRIBING OF DRUGS AND
17 DEVICES; OR
- 18 (III) INTERFERE WITH OR INTERVENE IN THE RELATIONSHIP
19 BETWEEN A PATIENT AND A PHARMACY;
- 20 (6) CHANGE, AMEND, REVISE, ADD, REMOVE, OR MODIFY ANY MATERIAL
21 TERMS, PROVISIONS, OR CONDITIONS OF ANY CONTRACT WITH A PHARMACY
22 PROVIDER AND ANY ACCOMPANYING PHARMACY SERVICES MANUALS OR
23 DOCUMENTS DURING THE TERM OF THE PHARMACY PROVIDER CONTRACT WITHOUT
24 THE EXPRESS WRITTEN CONSENT AND AGREEMENT OF THE PHARMACY PROVIDER;
- 25 (7) WITHHOLD, RECOUP, OR ATTEMPT TO RECOUP ANY FUNDS DUE TO A
26 PHARMACY PROVIDER FROM AN AUDIT THROUGH A SETOFF AGAINST FUTURE SUMS
27 DUE AND OWING TO A PHARMACY PROVIDER;
- 28 (8) RETROACTIVELY REVERSE OR DENY ACKNOWLEDGMENT OF
29 PARTICIPANT ELIGIBILITY, OR DENY OR ADJUST PAYMENTS AFTER ADJUDICATING
30 PHARMACY CLAIMS, EXCEPT FOR CIRCUMSTANCES IN WHICH THE PBM PROVIDES
31 EVIDENCE THAT:
- 32 (I) THE PAYMENT TO THE PHARMACY PROVIDER IS A DUPLICATE;
33 (II) THE CLAIM IS FRAUDULENT; OR
- 34 (III) THE PHARMACY DID NOT PROVIDE THE PRESCRIPTION
35 SERVICES TO THE ENROLLEE; OR
- 36 (9) OTHERWISE VIOLATE ANY PROVISION OF THIS SUBTITLE.

1 ~~45-1713.~~

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

4 ~~45-1714.~~

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 ~~45-1715.~~

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.~~

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

24 ~~45-1716.~~

25 ~~IN ADDITION TO THE PENALTIES AUTHORIZED IN § 45-1715 OF THIS SUBTITLE,~~
26 ~~THE COMMISSIONER OR THE STATE BOARD OF PHARMACY MAY ASSESS A CIVIL~~
27 ~~PENALTY, NOT EXCEEDING \$10,000, AGAINST ANY PERSON THAT VIOLATES THIS~~
28 ~~SUBTITLE.~~

29 ~~45-1717.~~

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 (B) "BENEFICIARY" MEANS AN INDIVIDUAL ON WHOSE BEHALF A PURCHASER
7 ENTERS INTO AN AGREEMENT WITH A PHARMACY BENEFITS MANAGER.

8 (C) "EXTRAPOLATION AUDIT" MEANS AN AUDIT OF A SAMPLE OF
9 PRESCRIPTION BENEFIT CLAIMS SUBMITTED BY A PHARMACY TO A PHARMACY
10 BENEFITS MANAGER OR ITS DESIGNATED CONTRACTOR OR AGENT THAT IS USED TO
11 ESTIMATE AUDIT RESULTS FOR A LARGER BATCH OR GROUP OF CLAIMS.

12 (D) "LABELER" MEANS A PERSON THAT:

13 (1) RECEIVES PRESCRIPTION DRUGS FROM A MANUFACTURER OR
14 WHOLESALE AND REPACKAGES THOSE DRUGS FOR LATER RETAIL SALE; AND

15 (2) HAS A LABELER CODE FROM THE FEDERAL FOOD AND DRUG
16 ADMINISTRATION UNDER 21 CFR § 207.20.

17 (E) (1) "PHARMACY BENEFITS MANAGEMENT SERVICES" MEANS THE
18 ADMINISTRATION OR MANAGEMENT OF PRESCRIPTION DRUG BENEFITS.

19 (2) "PHARMACY BENEFITS MANAGEMENT SERVICES" INCLUDES:

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

22 (II) PROCESSING OF PRESCRIPTION DRUG CLAIMS;

23 (III) ADMINISTRATION OF PAYMENTS RELATED TO PRESCRIPTION
24 DRUG CLAIMS; AND

25 (IV) NEGOTIATING OR ENTERING INTO CONTRACTUAL
26 ARRANGEMENTS WITH PHARMACY PROVIDERS.

27 (F) "PHARMACY BENEFITS MANAGER" MEANS A PERSON THAT PERFORMS
28 PHARMACY BENEFITS MANAGEMENT SERVICES.

29 (G) "PHARMACY PROVIDER" MEANS A PHARMACY OR A PHARMACIST.

30 (H) "PROSPECTIVE PURCHASER" MEANS A PERSON TO WHICH A PHARMACY
31 BENEFITS MANAGER OFFERS TO PROVIDE PHARMACY BENEFITS MANAGEMENT
32 SERVICES.

33 (I) (1) "PURCHASER" MEANS A PERSON THAT ENTERS INTO AN AGREEMENT
34 WITH A PHARMACY BENEFITS MANAGER FOR THE PROVISION OF PHARMACY
35 BENEFITS MANAGEMENT SERVICES.

1 (2) "PURCHASER" INCLUDES THE STATE.

2 (J) "TRADE SECRET" HAS THE MEANING STATED IN § 11-1201 OF THE
3 COMMERCIAL LAW ARTICLE.

4 (K) (1) "UTILIZATION REVIEW" HAS THE MEANING STATED IN § 15-10B-01 OF
5 THIS TITLE.

6 (2) "UTILIZATION REVIEW" INCLUDES:

7 (I) DRUG UTILIZATION MANAGEMENT;

8 (II) DRUG UTILIZATION REVIEW SERVICES; AND

9 (III) STEP PROTOCOL THERAPY MANAGEMENT.

10 15-1702.

11 (A) THE PROVISIONS OF THIS SUBTITLE DO NOT APPLY TO A MANAGED CARE
12 ORGANIZATION AUTHORIZED BY TITLE 15, SUBTITLE 1 OF THE HEALTH - GENERAL
13 ARTICLE.

14 (B) THE PROVISIONS OF §§ 15-1703 THROUGH 15-1717 OF THIS SUBTITLE DO
15 NOT APPLY TO AN INSURER, NONPROFIT HEALTH SERVICE PLAN, OR HEALTH
16 MAINTENANCE ORGANIZATION, OR AN AFFILIATE, SUBSIDIARY, OR OTHER RELATED
17 ENTITY OF AN INSURER, NONPROFIT HEALTH SERVICE PLAN, OR HEALTH
18 MAINTENANCE ORGANIZATION ACTING OR REPRESENTING ITSELF AS A PHARMACY
19 BENEFITS MANAGER IF:

20 (1) THE INSURER, NONPROFIT HEALTH SERVICE PLAN, OR HEALTH
21 MAINTENANCE ORGANIZATION OR THE AFFILIATE, SUBSIDIARY, OR OTHER RELATED
22 ENTITY OF THE INSURER, NONPROFIT HEALTH SERVICE PLAN, OR HEALTH
23 MAINTENANCE ORGANIZATION DIRECTLY OFFERS OR PROVIDES PHARMACY
24 BENEFITS MANAGEMENT SERVICES; AND

25 (2) THE PHARMACY BENEFITS MANAGEMENT SERVICES ARE OFFERED
26 OR PROVIDED ONLY TO ENROLLEES, SUBSCRIBERS, OR INSURED WHO ALSO ARE
27 COVERED BY HEALTH BENEFITS OFFERED OR PROVIDED BY THE INSURER,
28 NONPROFIT HEALTH SERVICE PLAN, OR HEALTH MAINTENANCE ORGANIZATION.

29 15-1703.

30 (A) A PERSON SHALL REGISTER WITH THE COMMISSIONER BEFORE THE
31 PERSON ACTS AS OR REPRESENTS ITSELF AS A PHARMACY BENEFITS MANAGER IN
32 THE STATE.

33 (B) AN APPLICANT FOR REGISTRATION SHALL:

34 (1) FILE WITH THE COMMISSIONER AN APPLICATION ON THE FORM
35 THAT THE COMMISSIONER PROVIDES; AND

1 (2) PAY TO THE COMMISSIONER A REGISTRATION FEE SET BY THE
2 COMMISSIONER.

3 (C) THE COMMISSIONER SHALL REGISTER EACH APPLICANT THAT MEETS
4 THE REQUIREMENTS ESTABLISHED BY THE COMMISSIONER BY REGULATION.

5 15-1704.

6 (A) A REGISTRATION EXPIRES AT THE END OF EVERY OTHER JUNE 30, UNLESS
7 IT IS RENEWED AS PROVIDED IN THIS SECTION.

8 (B) BEFORE A REGISTRATION EXPIRES, THE REGISTRANT MAY RENEW FOR AN
9 ADDITIONAL 2-YEAR TERM, IF THE REGISTRANT:

10 (1) OTHERWISE IS ENTITLED TO BE REGISTERED;

11 (2) FILES WITH THE COMMISSIONER A RENEWAL APPLICATION ON THE
12 FORM THE COMMISSIONER REQUIRES; AND

13 (3) PAYS TO THE COMMISSIONER A RENEWAL FEE AS SET BY THE
14 COMMISSIONER.

15 (C) AN APPLICATION FOR RENEWAL OF A REGISTRATION SHALL BE
16 CONSIDERED TIMELY IF POSTMARKED ON OR BEFORE JUNE 30 OF THE YEAR OF THE
17 RENEWAL.

18 15-1705.

19 A PHARMACY BENEFITS MANAGER MAY NOT:

20 (1) VIOLATE ANY PROVISION OF THIS ARTICLE;

21 (2) VIOLATE ANY REGULATION ADOPTED UNDER THIS SUBTITLE;

22 (3) KNOWINGLY FAIL TO COMPLY WITH AN ORDER OF THE
23 COMMISSIONER;

24 (4) FAIL TO MEET THE REQUIREMENTS FOR REGISTRATION
25 ESTABLISHED BY THE COMMISSIONER UNDER § 15-1703(C) OF THIS SUBTITLE;

26 (5) OBTAIN OR ATTEMPT TO OBTAIN A REGISTRATION BASED ON
27 INACCURATE INFORMATION;

28 (6) FRAUDULENTLY OR DECEPTIVELY OBTAIN OR USE A REGISTRATION;

29 (7) FAIL TO PROTECT THE CONFIDENTIALITY OF MEDICAL RECORDS IN
30 ACCORDANCE WITH APPLICABLE STATE AND FEDERAL LAWS; OR

31 (8) ACT AS A PHARMACY BENEFITS MANAGER WITHOUT FIRST
32 REGISTERING WITH THE COMMISSIONER.

1 15-1706.

2 (A) SUBJECT TO THE HEARING PROVISIONS OF TITLE 2 OF THIS ARTICLE, THE
3 COMMISSIONER MAY DENY A REGISTRATION TO AN APPLICANT OR REFUSE TO
4 RENEW, SUSPEND, OR REVOKE A REGISTRATION IF THE APPLICANT OR REGISTRANT
5 VIOLATES ANY PROVISION OF § 15-1705 OF THIS SUBTITLE.

6 (B) IF THE REGISTRATION OF A PHARMACY BENEFITS MANAGER IS
7 SUSPENDED OR REVOKED, THE COMMISSIONER, TO PROTECT THE INTERESTS OF
8 BENEFICIARIES AND PHARMACY PROVIDERS, MAY PERMIT THE CONTINUED
9 OPERATION OF THE PHARMACY BENEFITS MANAGER FOR A LIMITED PERIOD, NOT TO
10 EXCEED 60 DAYS, UNDER CONDITIONS AND RESTRICTIONS DETERMINED BY THE
11 COMMISSIONER.

12 15-1707.

13 (A) A PHARMACY BENEFITS MANAGER SHALL REGISTER WITH THE
14 COMMISSIONER AS A THIRD PARTY ADMINISTRATOR UNDER TITLE 8, SUBTITLE 3 OF
15 THIS ARTICLE IF THE PHARMACY BENEFITS MANAGER:

16 (1) PROCESSES PRESCRIPTION DRUG CLAIMS; OR

17 (2) ADMINISTERS PAYMENTS RELATED TO PRESCRIPTION DRUG
18 CLAIMS.

19 (B) A PHARMACY BENEFITS MANAGER THAT PROCESSES PRESCRIPTION DRUG
20 CLAIMS OR ADMINISTERS PAYMENTS RELATED TO PRESCRIPTION DRUG CLAIMS
21 SHALL:

22 (1) PAY CLAIMS IN ACCORDANCE WITH § 15-1005 OF THIS TITLE; AND

23 (2) ADJUST CLAIMS IN ACCORDANCE WITH § 15-1008 OF THIS TITLE.

24 15-1708.

25 A PHARMACY BENEFITS MANAGER THAT CONDUCTS UTILIZATION REVIEW
26 SHALL OBTAIN FROM THE COMMISSIONER A CERTIFICATE OF REGISTRATION AS A
27 PRIVATE REVIEW AGENT UNDER SUBTITLE 10B OF THIS TITLE.

28 15-1709.

29 EXCEPT AS PROVIDED IN § 15-1702 OF THIS SUBTITLE, AN INSURER, NONPROFIT
30 HEALTH SERVICE PLAN, OR HEALTH MAINTENANCE ORGANIZATION MAY NOT ENTER
31 INTO AN AGREEMENT WITH A PHARMACY BENEFITS MANAGER THAT HAS NOT
32 REGISTERED WITH THE COMMISSIONER.

33 15-1710.

34 (A) WHENEVER THE COMMISSIONER CONSIDERS IT ADVISABLE, THE
35 COMMISSIONER SHALL EXAMINE THE AFFAIRS, TRANSACTIONS, ACCOUNTS,
36 RECORDS, AND ASSETS OF EACH PHARMACY BENEFITS MANAGER.

1 (B) THE EXAMINATION SHALL BE CONDUCTED IN ACCORDANCE WITH § 2-207
2 OF THIS ARTICLE.

3 (C) THE EXPENSE OF THE EXAMINATION SHALL BE PAID IN ACCORDANCE
4 WITH § 2-208 OF THIS ARTICLE.

5 (D) THE REPORTS OF THE EXAMINATION AND INVESTIGATION SHALL BE
6 ISSUED IN ACCORDANCE WITH § 2-209 OF THIS ARTICLE.

7 15-1711.

8 A PHARMACY BENEFITS MANAGER SHALL MAINTAIN ADEQUATE BOOKS AND
9 RECORDS ABOUT EACH PURCHASER FOR WHICH THE PHARMACY BENEFITS
10 MANAGER PROVIDES PHARMACY BENEFITS MANAGEMENT SERVICES:

11 (1) IN ACCORDANCE WITH PRUDENT STANDARDS OF RECORD KEEPING;

12 (2) FOR THE DURATION OF THE AGREEMENT BETWEEN THE PHARMACY
13 BENEFITS MANAGER AND THE PURCHASER; AND

14 (3) FOR 3 YEARS AFTER THE PHARMACY BENEFITS MANAGER CEASES
15 TO PROVIDE PHARMACY BENEFITS MANAGEMENT SERVICES TO THE PURCHASER.

16 15-1712.

17 ON OR BEFORE APRIL 1, 2006, THE COMMISSIONER SHALL ADOPT REGULATIONS
18 TO IMPLEMENT THIS SUBTITLE.

19 15-1713.

20 (A) A PHARMACY BENEFITS MANAGER SHALL DISCLOSE TO A PROSPECTIVE
21 PURCHASER IN WRITING:

22 (1) THE AMOUNT OF ALL REBATES, ADMINISTRATIVE FEES, DETAILING
23 PAYMENTS, EDUCATIONAL PAYMENTS, AND OTHER RETROSPECTIVE DISCOUNTS
24 THAT THE PHARMACY BENEFITS MANAGER ESTIMATES IT WOULD RECEIVE,
25 DIRECTLY OR INDIRECTLY, FROM PHARMACEUTICAL MANUFACTURERS OR
26 LABELERS IN CONNECTION WITH PRESCRIPTION DRUG BENEFITS RELATED TO THE
27 PROSPECTIVE PURCHASER, IF THE PROSPECTIVE PURCHASER WERE TO CONTRACT
28 WITH THE PHARMACY BENEFITS MANAGER;

29 (2) THE NATURE, TYPE, AND AMOUNT OF ALL OTHER REVENUE THAT
30 THE PHARMACY BENEFITS MANAGER ESTIMATES IT WOULD RECEIVE, DIRECTLY OR
31 INDIRECTLY, FROM PHARMACEUTICAL MANUFACTURERS OR LABELERS IN
32 CONNECTION WITH PRESCRIPTION DRUG BENEFITS RELATED TO THE PROSPECTIVE
33 PURCHASER, IF THE PROSPECTIVE PURCHASER WERE TO CONTRACT WITH THE
34 PHARMACY BENEFITS MANAGER;

35 (3) ANY ADMINISTRATIVE OR OTHER FEES THAT WOULD BE CHARGED
36 BY THE PHARMACY BENEFITS MANAGER TO THE PROSPECTIVE PURCHASER;

1 (4) ANY ARRANGEMENTS WITH PRESCRIBING PROVIDERS, MEDICAL
2 GROUPS, INDIVIDUAL PRACTICE ASSOCIATIONS, PHARMACY PROVIDERS, OR OTHER
3 PERSONS THAT ARE ASSOCIATED WITH ACTIVITIES OF THE PHARMACY BENEFITS
4 MANAGER TO ENCOURAGE FORMULARY COMPLIANCE OR OTHERWISE MANAGE
5 PRESCRIPTION DRUG BENEFITS; AND

6 (5) A LIST OF ANY DRUGS THAT THE PHARMACY BENEFITS MANAGER,
7 DIRECTLY OR INDIRECTLY, REPACKAGED AND ASSIGNED NEW OR DIFFERENT
8 NATIONAL DRUG CODE NUMBERS INCLUDING, FOR EACH DRUG ON THE LIST:

9 (I) THE DRUG NAME AND STRENGTH;

10 (II) THE ORIGINAL NATIONAL DRUG CODE NUMBER AND THE NEW
11 NATIONAL DRUG CODE NUMBER; AND

12 (III) THE ORIGINAL PRICE AND THE NEW PRICE.

13 (B) THE DISCLOSURE REQUIRED UNDER SUBSECTION (A)(1) OF THIS SECTION
14 SHALL BE PROVIDED:

15 (1) IN THE AGGREGATE;

16 (2) FOR EACH THERAPEUTIC CLASS OF DRUGS ON A LIST OF SPECIFIED
17 THERAPEUTIC CLASSES; AND

18 (3) FOR FIVE INDIVIDUAL PRESCRIBED DRUGS IN EACH THERAPEUTIC
19 CLASS OF DRUGS AS REQUESTED BY THE PURCHASER.

20 (C) A THERAPEUTIC CLASS SHALL INCLUDE AT LEAST TWO DRUGS.

21 15-1714.

22 (A) AT LEAST QUARTERLY, A PHARMACY BENEFITS MANAGER SHALL
23 DISCLOSE TO A PURCHASER IN WRITING:

24 (1) THE AMOUNT OF ALL REBATES, ADMINISTRATIVE FEES, DETAILING
25 PAYMENTS, EDUCATIONAL PROGRAMS, AND OTHER RETROSPECTIVE DISCOUNTS
26 THAT THE PHARMACY BENEFITS MANAGER RECEIVES, DIRECTLY OR INDIRECTLY,
27 FROM PHARMACEUTICAL MANUFACTURERS OR LABELERS IN CONNECTION WITH
28 PRESCRIPTION DRUG BENEFITS SPECIFIC TO THE PURCHASER;

29 (2) THE NATURE, TYPE, AND AMOUNT OF ALL OTHER REVENUE THAT
30 THE PHARMACY BENEFITS MANAGER RECEIVES, DIRECTLY OR INDIRECTLY, FROM
31 PHARMACEUTICAL MANUFACTURERS OR LABELERS IN CONNECTION WITH
32 PRESCRIPTION DRUG BENEFITS RELATED TO THE PURCHASER;

33 (3) ANY PRESCRIPTION DRUG UTILIZATION INFORMATION RELATED TO
34 UTILIZATION BY THE PURCHASER'S BENEFICIARIES OR AGGREGATE UTILIZATION
35 DATA THAT IS NOT SPECIFIC TO AN INDIVIDUAL BENEFICIARY, PRESCRIBER, OR
36 PURCHASER;

1 (4) ANY ADMINISTRATIVE OR OTHER FEES CHARGED BY THE PHARMACY
2 BENEFITS MANAGER TO THE PURCHASER;

3 (5) ANY ARRANGEMENTS WITH PRESCRIBING PROVIDERS, MEDICAL
4 GROUPS, INDIVIDUAL PRACTICE ASSOCIATIONS, PHARMACY PROVIDERS, OR OTHER
5 PERSONS THAT ARE ASSOCIATED WITH ACTIVITIES OF THE PHARMACY BENEFITS
6 MANAGER TO ENCOURAGE FORMULARY COMPLIANCE OR OTHERWISE MANAGE
7 PRESCRIPTION DRUG BENEFITS;

8 (6) A LIST OF ANY DRUGS THAT THE PHARMACY BENEFITS MANAGER,
9 DIRECTLY OR INDIRECTLY, REPACKAGED AND ASSIGNED NEW OR DIFFERENT
10 NATIONAL DRUG CODE NUMBERS INCLUDING, FOR EACH DRUG ON THE LIST:

11 (I) THE DRUG NAME AND STRENGTH;

12 (II) THE ORIGINAL NATIONAL DRUG CODE NUMBER AND THE NEW
13 NATIONAL DRUG CODE NUMBER; AND

14 (III) THE ORIGINAL PRICE AND THE NEW PRICE; AND

15 (7) A LIST OF PRESCRIPTIONS FOR WHICH THERE WAS A DIFFERENCE
16 BETWEEN THE PRICE PAID TO A RETAIL PHARMACY AND THE AMOUNT THAT WAS
17 BILLED TO THE PURCHASER INCLUDING, FOR EACH PRESCRIPTION:

18 (I) THE PRESCRIPTION NUMBER;

19 (II) THE DATE THE PRESCRIPTION WAS PROCESSED BY THE
20 PHARMACY BENEFITS MANAGER;

21 (III) THE NATIONAL DRUG CODE NUMBER;

22 (IV) THE BENEFICIARY'S NAME; AND

23 (V) THE PRICE PAID TO THE RETAIL PHARMACY AND THE AMOUNT
24 BILLED TO THE PURCHASER.

25 (B) THE DISCLOSURE REQUIRED UNDER SUBSECTION (A)(1) OF THIS SECTION
26 SHALL BE PROVIDED:

27 (1) IN THE AGGREGATE;

28 (2) FOR EACH THERAPEUTIC CLASS OF DRUGS ON A LIST OF SPECIFIED
29 THERAPEUTIC CLASSES; AND

30 (3) FOR FIVE INDIVIDUAL PRESCRIBED DRUGS IN EACH THERAPEUTIC
31 CLASS OF DRUGS AS REQUESTED BY THE PURCHASER.

32 (C) A THERAPEUTIC CLASS SHALL INCLUDE AT LEAST TWO DRUGS.

1 15-1715.

2 (A) EXCEPT FOR UTILIZATION INFORMATION, AND EXCEPT AS PROVIDED IN
3 SUBSECTION (D) OF THIS SECTION, A PHARMACY BENEFITS MANAGER NEED NOT
4 MAKE THE DISCLOSURES REQUIRED UNDER §§ 15-1713 AND 15-1714 OF THIS
5 SUBTITLE UNLESS AND UNTIL THE PROSPECTIVE PURCHASER OR THE PURCHASER
6 AGREES IN WRITING TO MAINTAIN AS CONFIDENTIAL ANY PROPRIETARY
7 INFORMATION DISCLOSED BY THE PHARMACY BENEFITS MANAGER.

8 (B) THE AGREEMENT UNDER SUBSECTION (A) OF THIS SECTION MAY:

9 (1) PROVIDE FOR EQUITABLE AND LEGAL REMEDIES IN THE EVENT OF A
10 VIOLATION OF THE AGREEMENT; AND

11 (2) INCLUDE PERSONS WITH WHICH THE PROSPECTIVE PURCHASER OR
12 PURCHASER CONTRACTS TO PROVIDE CONSULTING SERVICES RELATING TO
13 PHARMACY BENEFITS MANAGEMENT SERVICES.

14 (C) PROPRIETARY INFORMATION INCLUDES:

15 (1) TRADE SECRETS; AND

16 (2) INFORMATION ABOUT PRICING, COSTS, REVENUES, TAXES, MARKET
17 SHARE, NEGOTIATING STRATEGIES, CUSTOMERS, AND PERSONNEL HELD BY A
18 PHARMACY BENEFITS MANAGER AND USED FOR ITS BUSINESS PURPOSES.

19 (D) THIS SECTION DOES NOT REDUCE THE AUTHORITY OF THE OFFICE OF
20 THE ATTORNEY GENERAL OR THE COMMISSIONER TO OBTAIN INFORMATION AND
21 USE THE INFORMATION IN ANY PROCEEDING.

22 15-1716.

23 A CONTRACT EXECUTED BY A PHARMACY BENEFITS MANAGER FOR THE
24 PROVISION OF PHARMACY BENEFITS MANAGEMENT SERVICES SHALL INCLUDE:

25 (1) THE AMOUNT OF THE TOTAL REVENUES, REBATES, AND DISCOUNTS
26 IDENTIFIED IN §§ 15-1713 AND 15-1714 OF THIS SUBTITLE THAT WILL BE PASSED ON
27 TO THE PURCHASER;

28 (2) THE MAXIMUM ALLOWABLE COST AND AVERAGE WHOLESALE PRICE
29 RESOURCES USED TO DETERMINE THE PRICE PAID TO A PHARMACY AND BILLED TO
30 THE PURCHASER;

31 (3) THE CONDITIONS UNDER WHICH BENEFICIARY UTILIZATION DATA
32 MAY BE DISCLOSED OR SOLD BY THE PHARMACY BENEFITS MANAGER TO ANY
33 PERSON OTHER THAN THE PURCHASER;

34 (4) ANY ADMINISTRATIVE OR OTHER FEES:

35 (I) CHARGED BY THE PHARMACY BENEFITS MANAGER TO THE
36 PURCHASER; OR

1 (II) COLLECTED BY THE PHARMACY BENEFITS MANAGER ON
2 BEHALF OF THE PURCHASER;

3 (5) (I) THE CONDITIONS UNDER WHICH AN AUDIT WILL BE
4 CONDUCTED OF THE CONTRACT FOR PHARMACY BENEFITS MANAGEMENT
5 SERVICES;

6 (II) WHO WILL CONDUCT THE AUDIT; AND

7 (III) WHO WILL PAY FOR THE AUDIT;

8 (6) ANY REVENUES, REBATES, OR DISCOUNTS RECEIVED, DIRECTLY OR
9 INDIRECTLY, BY THE PHARMACY BENEFITS MANAGER FROM PERSONS OTHER THAN
10 PHARMACEUTICAL MANUFACTURERS AND LABELERS THAT ARE RELATED TO THE
11 PHARMACY BENEFITS MANAGEMENT SERVICES TO BE PROVIDED TO THE
12 PURCHASER;

13 (7) THE PROCESS FOR THE DEVELOPMENT OF FORMULARIES,
14 NOTIFICATION OF CHANGES TO FORMULARIES, AND APPROVAL OF CHANGES BY THE
15 PURCHASER; AND

16 (8) AN AGREEMENT TO PROVIDE TO THE PURCHASER A LIST OF
17 PRESCRIPTIONS FOR WHICH THERE WAS A DIFFERENCE BETWEEN THE PRICE PAID
18 TO A RETAIL PHARMACY AND THE AMOUNT THAT WILL BE OR WAS BILLED TO THE
19 PURCHASER INCLUDING, FOR EACH PRESCRIPTION:

20 (I) THE PRESCRIPTION NUMBER;

21 (II) THE DATE THE PRESCRIPTION DRUG WAS PROCESSED BY THE
22 PHARMACY BENEFITS MANAGER;

23 (III) THE NATIONAL DRUG CODE NUMBER;

24 (IV) THE BENEFICIARY'S NAME; AND

25 (V) THE PRICE PAID TO THE RETAIL PHARMACY AND THE AMOUNT
26 BILLED TO THE PURCHASER.

27 15-1717.

28 (A) (1) EACH MEMBER OF A PHARMACY AND THERAPEUTICS COMMITTEE
29 FOR A PHARMACY BENEFITS MANAGER SHALL BE:

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

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

33 (2) A MAJORITY OF COMMITTEE MEMBERS MAY NOT BE EMPLOYED BY
34 THE PHARMACY BENEFITS MANAGER.

1 (B) A PHARMACY AND THERAPEUTICS COMMITTEE MEMBER MAY NOT:

2 (1) BE AN OFFICER, EMPLOYEE, DIRECTOR, OR AGENT OF A
3 PHARMACEUTICAL MANUFACTURER; OR

4 (2) HAVE A FINANCIAL INTEREST IN A PHARMACEUTICAL
5 MANUFACTURER, OTHER THAN OWNERSHIP OF A NOMINAL NUMBER OF SHARES OF
6 THE PHARMACEUTICAL MANUFACTURER'S STOCK, PURCHASED ON A NATIONAL
7 SECURITIES EXCHANGE.

8 15-1718.

9 (A) A PHARMACY BENEFITS MANAGER MAY NOT SUBSTITUTE ANOTHER
10 PRESCRIPTION DRUG FOR THE DRUG ORIGINALLY PRESCRIBED UNLESS:

11 (1) THE SUBSTITUTION IS MADE FOR MEDICAL REASONS THAT BENEFIT
12 THE BENEFICIARY; OR

13 (2) THE SUBSTITUTION RESULTS IN FINANCIAL SAVINGS AND BENEFITS
14 TO THE PURCHASER.

15 (B) IF A PRESCRIPTION DRUG SUBSTITUTION IS MADE UNDER THIS SECTION,
16 THE PHARMACY BENEFITS MANAGER SHALL DISCLOSE TO THE PURCHASER ANY
17 BENEFIT OR PAYMENT RECEIVED IN ANY FORM BY THE PHARMACY BENEFITS
18 MANAGER FROM A PHARMACEUTICAL MANUFACTURER OR OTHER PERSON RELATED
19 TO THE SUBSTITUTION.

20 15-1719.

21 (A) EXCEPT AS PROVIDED IN SUBSECTION (C) OF THIS SECTION, A PHARMACY
22 BENEFITS MANAGER SHALL:

23 (1) OBTAIN AUTHORIZATION FROM A PRESCRIBER TO SUBSTITUTE A
24 PRESCRIPTION DRUG; AND

25 (2) DISCLOSE TO THE PRESCRIBER:

26 (I) THE COST SAVINGS FOR THE PURCHASER, IF ANY, THAT RESULT
27 FROM THE DRUG SUBSTITUTION;

28 (II) THE DIFFERENCE, IF ANY, IN COPAYMENTS OR OTHER
29 OUT-OF-POCKET COSTS PAID BY THE BENEFICIARY TO OBTAIN THE SUBSTITUTE
30 DRUG;

31 (III) THE EXISTENCE OF ADDITIONAL PAYMENTS RECEIVED BY THE
32 PHARMACY BENEFITS MANAGER THAT ARE NOT REFLECTED IN THE COST SAVINGS
33 TO THE PURCHASER;

34 (IV) THE CIRCUMSTANCES, IF ANY, UNDER WHICH THE CURRENTLY
35 PRESCRIBED DRUG WILL BE COVERED;

1 (V) THE CIRCUMSTANCES, IF ANY, AND EXTENT TO WHICH HEALTH
2 CARE COSTS RELATED TO THE DRUG SUBSTITUTION WILL BE COMPENSATED; AND

3 (VI) ANY KNOWN DIFFERENCES IN POTENTIAL EFFECTS ON A
4 BENEFICIARY'S HEALTH AND SAFETY, INCLUDING SIDE EFFECTS.

5 (B) IF AUTHORIZATION IS GIVEN VERBALLY, A PHARMACY BENEFITS
6 MANAGER SHALL RECORD THE NAME AND TITLE OF THE PRESCRIBER AUTHORIZING
7 THE PRESCRIPTION DRUG SUBSTITUTION.

8 (C) A PHARMACY BENEFITS MANAGER MAY MAKE A PRESCRIPTION DRUG
9 SUBSTITUTION WITHOUT OBTAINING AUTHORIZATION FROM A PRESCRIBER OR
10 MAKING THE DISCLOSURES REQUIRED UNDER SUBSECTION (A) OF THIS SECTION IF:

11 (1) THE SUBSTITUTION IS FROM A BRAND NAME DRUG TO A GENERIC
12 DRUG, AND THE SUBSTITUTION IS MADE IN ACCORDANCE WITH § 12-504 OF THE
13 HEALTH OCCUPATIONS ARTICLE;

14 (2) THE CURRENTLY PRESCRIBED DRUG IS NO LONGER AVAILABLE IN
15 THE MARKET; OR

16 (3) THE SUBSTITUTION IS REQUIRED FOR COVERAGE REASONS
17 BECAUSE THE PRESCRIBED DRUG IS NOT COVERED BY THE BENEFICIARY'S
18 FORMULARY OR PLAN.

19 (D) A PHARMACY BENEFITS MANAGER MAY NOT SUBSTITUTE A
20 PRESCRIPTION DRUG FOR A CURRENTLY PRESCRIBED PRESCRIPTION DRUG UNLESS
21 THE PHARMACY BENEFITS MANAGER PROVIDES THE BENEFICIARY OR THE
22 BENEFICIARY'S REPRESENTATIVE THE FOLLOWING:

23 (1) UNLESS THE SUBSTITUTION WAS EXEMPTED UNDER SUBSECTION
24 (C) OF THIS SECTION, A NOTIFICATION THAT:

25 (I) THE PHARMACY BENEFITS MANAGER REQUESTED A DRUG
26 SUBSTITUTION BY CONTACTING THE BENEFICIARY'S PRESCRIBER; AND

27 (II) THE PRESCRIBER APPROVED THE DRUG SUBSTITUTION;

28 (2) THE NAMES OF THE PROPOSED DRUG SUBSTITUTION AND THE
29 CURRENTLY PRESCRIBED DRUG;

30 (3) THE DIFFERENCE, IF ANY, IN COPAYMENTS OR OTHER
31 OUT-OF-POCKET COSTS PAID BY THE BENEFICIARY TO OBTAIN THE SUBSTITUTE
32 DRUG;

33 (4) ANY KNOWN DIFFERENCES IN POTENTIAL EFFECTS ON A
34 BENEFICIARY'S HEALTH AND SAFETY, INCLUDING SIDE EFFECTS;

35 (5) THE CIRCUMSTANCES, IF ANY, UNDER WHICH THE CURRENTLY
36 PRESCRIBED DRUG WILL BE COVERED;

1 (6) THE CIRCUMSTANCES, IF ANY, AND THE EXTENT TO WHICH HEALTH
2 CARE COSTS RELATED TO THE DRUG SUBSTITUTION WILL BE COMPENSATED;

3 (7) A NOTIFICATION THAT THE BENEFICIARY MAY DECLINE THE DRUG
4 SUBSTITUTION IF THE CURRENTLY PRESCRIBED DRUG REMAINS ON THE
5 BENEFICIARY'S FORMULARY, AND THE BENEFICIARY IS WILLING TO PAY ANY
6 DIFFERENCE IN THE COPAYMENT AMOUNT; AND

7 (8) A TOLL-FREE TELEPHONE NUMBER TO COMMUNICATE WITH THE
8 PHARMACY BENEFITS MANAGER.

9 (E) (1) A PHARMACY BENEFITS MANAGER SHALL CANCEL AND REVERSE
10 THE PRESCRIPTION DRUG SUBSTITUTION ON WRITTEN OR VERBAL INSTRUCTIONS
11 FROM A PRESCRIBER, THE BENEFICIARY, OR THE BENEFICIARY'S REPRESENTATIVE.

12 (2) IF A PRESCRIBER, THE BENEFICIARY, OR THE BENEFICIARY'S
13 REPRESENTATIVE CANCELS AND REVERSES A DRUG SUBSTITUTION, THE PHARMACY
14 BENEFITS MANAGER SHALL:

15 (I) OBTAIN A PRESCRIPTION FOR AND DISPENSE THE CURRENTLY
16 PRESCRIBED DRUG;

17 (II) CHARGE THE BENEFICIARY ONLY ONE COPAYMENT; AND

18 (III) IF A BENEFICIARY WILL EXHAUST THE SUPPLY OF THE
19 CURRENTLY PRESCRIBED DRUG BEFORE A REPLACEMENT SHIPMENT WILL ARRIVE
20 TO THE BENEFICIARY, ARRANGE FOR DISPENSING OF AN APPROPRIATE QUANTITY
21 OF REPLACEMENT DRUGS AT A RETAIL OR INSTITUTIONAL PHARMACY AT NO
22 ADDITIONAL COST TO THE BENEFICIARY.

23 (3) A PHARMACY BENEFITS MANAGER MAY NOT BE REQUIRED TO
24 CANCEL AND REVERSE A DRUG SUBSTITUTION IF THE PRESCRIBED DRUG IS NO
25 LONGER ON THE PURCHASER'S FORMULARY OR THE BENEFICIARY IS UNWILLING TO
26 PAY A HIGHER COPAYMENT OR OTHER COST ASSOCIATED WITH THE PRESCRIBED
27 DRUG.

28 (F) A PHARMACY BENEFITS MANAGER SHALL MAINTAIN A TOLL-FREE
29 TELEPHONE NUMBER 24 HOURS A DAY, 7 DAYS A WEEK, FOR PRESCRIBERS,
30 PHARMACY PROVIDERS, AND BENEFICIARIES.

31 15-1720.

32 (A) IF THE PHARMACY BENEFITS MANAGEMENT SERVICES PERFORMED BY A
33 PHARMACY BENEFITS MANAGER FOR A PURCHASER INCLUDE NEGOTIATING OR
34 ENTERING INTO CONTRACTUAL ARRANGEMENTS WITH PHARMACY PROVIDERS,
35 BEFORE THE PHARMACY BENEFITS MANAGER MAY PROVIDE PHARMACY BENEFITS
36 MANAGEMENT SERVICES FOR THE PURCHASER, THE PHARMACY BENEFITS
37 MANAGER SHALL ENTER INTO ANY NECESSARY WRITTEN CONTRACTS WITH
38 PHARMACY PROVIDERS.

1 (B) A WRITTEN CONTRACT SHALL REQUIRE THE PHARMACY BENEFITS
2 MANAGER TO:

3 (1) DISCLOSE TO PHARMACY PROVIDERS:

4 (I) THE TERMS, CONDITIONS, FEES, BENEFIT DESIGNS, PROCESS,
5 AND PROCEDURES FOR ACCESSING THE PHARMACY BENEFITS MANAGEMENT
6 SERVICES PROVIDED BY THE PHARMACY BENEFITS MANAGER; AND

7 (II) THE PHARMACY BENEFITS MANAGER'S PROCEDURES FOR
8 HANDLING DISPUTES;

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

13 (3) STIPULATE THAT PHARMACY PROVIDERS WILL NOT BE REQUIRED TO
14 AGREE TO EXTRAPOLATION AUDITS AS A CONDITION OF ENTERING INTO THE
15 CONTRACT OR PARTICIPATING IN THE PHARMACY BENEFITS MANAGER'S NETWORK.
16 15-1721.

17 A PHARMACY BENEFITS MANAGER:

18 (1) SHALL ALLOW A BENEFICIARY TO OBTAIN COVERED PHARMACY
19 SERVICES FROM THE PHARMACY PROVIDER OF THE BENEFICIARY'S CHOICE WITHIN
20 THE PHARMACY BENEFITS MANAGER'S NETWORK;

21 (2) SHALL ALLOW A RETAIL OR INSTITUTIONAL PHARMACY THAT CAN
22 MEET THE SAME TERMS AND CONDITIONS AS A MAIL ORDER PHARMACY TO PROVIDE
23 THE SAME SERVICES PROVIDED BY A MAIL ORDER PHARMACY; AND

24 (3) MAY NOT:

25 (I) REQUIRE A BENEFICIARY TO OBTAIN PHARMACY SERVICES
26 FROM A MAIL ORDER PHARMACY, IF A RETAIL OR INSTITUTIONAL PHARMACY CAN
27 MEET THE SAME TERMS AND CONDITIONS AS A MAIL ORDER PHARMACY;

28 (II) USE ANY FINANCIAL OR OTHER DISINCENTIVES, PENALTIES,
29 OR OTHER MEANS TO INFLUENCE, COERCE, OR STEER BENEFICIARIES AWAY FROM A
30 RETAIL OR INSTITUTIONAL PHARMACY THAT CAN MEET THE SAME TERMS AND
31 CONDITIONS AS A MAIL ORDER PHARMACY; OR

32 (III) LIMIT THE QUANTITY OF DRUGS THAT A BENEFICIARY MAY
33 OBTAIN AT ANY ONE TIME FROM ANY TYPE OF PHARMACY PROVIDER, UNLESS THE
34 LIMIT IS APPLIED UNIFORMLY TO ALL PHARMACY PROVIDERS THAT ARE WITHIN THE
35 PHARMACY BENEFITS MANAGER'S NETWORK, UNDER CONTRACT, OR OTHERWISE
36 AUTHORIZED TO PROVIDE PHARMACY SERVICES TO BENEFICIARIES.

1 15-1722.

2 ALL DISCLOSURES MADE UNDER THIS SUBTITLE SHALL COMPLY WITH THE
3 PRIVACY STANDARDS OF THE FEDERAL HEALTH INSURANCE PORTABILITY AND
4 ACCOUNTABILITY ACT.

5 15-1723.

6 IN ADDITION TO THE PENALTIES AUTHORIZED BY § 15-1706 OF THIS SUBTITLE,
7 THE COMMISSIONER MAY ASSESS A CIVIL PENALTY NOT EXCEEDING \$10,000 AGAINST
8 ANY PERSON THAT VIOLATES THIS SUBTITLE.

9 **Article - Health Occupations**

10 12-101.

11 (k) (1) "Nonresident pharmacy" means a pharmacy located outside this
12 State that, in the normal course of business, as determined by the Board, ships, mails,
13 or delivers drugs or devices to a person in this State pursuant to a prescription.

14 (2) "NONRESIDENT PHARMACY" INCLUDES A PHARMACY BENEFITS
15 MANAGER, LOCATED WITHIN OR OUTSIDE THIS STATE, THAT IS REGULATED UNDER
16 TITLE 15, SUBTITLE 17 OF THE INSURANCE ARTICLE, IF THE PHARMACY BENEFITS
17 MANAGER SHIPS, MAILES, OR DELIVERS DRUGS OR DEVICES TO A PERSON IN THIS
18 STATE PURSUANT TO A PRESCRIPTION.

19 12-403.

20 (a) This section does not require a nonresident pharmacy to violate the laws or
21 regulations of the state in which it is located.

22 (b) Except as otherwise provided in this section, a pharmacy for which a
23 pharmacy permit has been issued under this title:

24 (17) With regard to a prescription drug that is delivered in this State by
25 the United States mail, a common carrier, or a delivery service and is not personally
26 hand delivered directly to a patient or to the agent of the patient at the residence of
27 the patient or at another location designated by the patient, shall:

28 (i) Provide a general written notice in each shipment of a
29 prescription drug that alerts a consumer that, under certain circumstances, a
30 medication's effectiveness may be affected by exposure to extremes of heat, cold, or
31 humidity; and

32 (ii) Provide a specific written notice in each shipment of a
33 prescription drug that provides a consumer with a toll-free or local consumer access
34 telephone number accessible during regular hours of operation, which is designed to
35 respond to consumer questions pertaining to medications; and

1 (d) A nonresident pharmacy shall hold a pharmacy permit issued by the
2 Board.

3 (e) (1) In order to obtain a pharmacy permit from the Board, a nonresident
4 pharmacy, TO THE EXTENT APPLICABLE, shall:

5 (i) Submit an application to the Board on the form that the Board
6 requires;

7 (ii) Pay to the Board an application fee set by the Board;

8 (iii) Submit a copy of the most recent inspection report resulting
9 from an inspection conducted by the regulatory or licensing agency of the state in
10 which the nonresident pharmacy is located; and

11 (iv) On the required permit application, identify the name and
12 current address of an agent located in this State officially designated to accept service
13 of process.

14 (2) A nonresident pharmacy shall report a change in the name or address
15 of the resident agent in writing to the Board 30 days prior to the change.

16 (f) A nonresident pharmacy, TO THE EXTENT APPLICABLE, shall:

17 (1) Comply with the laws of the state in which it is located;

18 (2) On an annual basis and within 30 days after a change of office,
19 corporate officer, or pharmacist, disclose to the Board the location, names, and titles
20 of all principal corporate officers and all pharmacists who are dispensing
21 prescriptions for drugs or devices to persons in this State;

22 (3) Comply with all lawful directions and requests for information from
23 the regulatory or licensing agency of the state in which it is located and all requests
24 for information made by the Board pursuant to this section;

25 (4) Maintain at all times a valid, unexpired permit to conduct a
26 pharmacy in compliance with the laws of the state in which it is located;

27 (5) Maintain its records of prescription drugs or devices dispensed to
28 patients in this State so that the records are readily retrievable;

29 (6) During its regular hours of operation, but not less than 6 days a
30 week, and for a minimum of 40 hours per week, provide toll-free telephone service to
31 facilitate communication between patients in this State and a pharmacist who has
32 access to the patient's prescription records;

33 (7) Disclose its toll-free telephone number on a label affixed to each
34 container of drugs or devices;

1 (8) Comply with the laws of this State relating to the confidentiality of
2 prescription records if there are no laws relating to the confidentiality of prescription
3 records in the state in which the nonresident pharmacy is located; [and]

4 (9) Comply with the requirements of subsection (b)(17) of this section;
5 AND

6 (10) REQUIRE EACH EMPLOYEE OR CONTRACTOR TO BE LICENSED TO
7 PRACTICE PHARMACY IF THE EMPLOYEE OR CONTRACTOR PRACTICES PHARMACY
8 FOR OR ON BEHALF OF THE NONRESIDENT PHARMACY.

9 (g) Subject to the hearing provisions of § 12-411 of this title, if a pharmacy or
10 a nonresident pharmacy is operated in violation of this section, the Board may
11 suspend the applicable pharmacy permit until the pharmacy complies with this
12 section.

13 ~~SECTION 2.~~ AND BE IT FURTHER ENACTED, That a person acting as a
14 pharmacy benefits manager in the State on the effective date of this Act may continue
15 to act as a pharmacy benefits manager in the State without being registered with the
16 Maryland Insurance Commissioner, as required under Section 1 of this Act, if the
17 person:

18 (1) registers with the Commissioner on or before September 1, 2006; and

19 (2) complies with all other applicable provisions of this Act.

20 ~~SECTION 2.~~ 3. AND BE IT FURTHER ENACTED, That this Act shall take
21 effect October 1, 2005.