

SENATE BILL 723

J3

(8lr2240)

ENROLLED BILL

—Finance/Health and Government Operations—

Introduced by **Senators Klausmeier, Della, and Pugh**

Read and Examined by Proofreaders:

Proofreader.

Proofreader.

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

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

President.

CHAPTER _____

1 AN ACT concerning

2 **Pharmacy Benefits Managers - ~~Prescription Drug Substitution~~ Therapeutic**
3 **Interchanges**

4 FOR the purpose of prohibiting a pharmacy benefits manager ~~from substituting one~~
5 ~~prescription drug for the drug originally prescribed~~ or its agent from requesting
6 a therapeutic interchange unless certain conditions are met; requiring a
7 ~~pharmacy benefits manager to disclose certain information to a purchaser if a~~
8 ~~drug substitution is made;~~ requiring a pharmacy benefits manager or its agent
9 to obtain a certain authorization to make a ~~drug substitution~~ therapeutic
10 interchange and to make certain disclosures to a prescriber; ~~providing for~~
11 ~~certain exceptions; prohibiting a pharmacy benefits manager from substituting~~
12 ~~a drug for a currently prescribed drug unless the pharmacy benefits manager~~
13 ~~provides a beneficiary or the beneficiary's representative with certain~~
14 ~~information~~ requiring a pharmacy benefits manager or its agent to disclose
15 certain information to a beneficiary and include a certain insert and a certain

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.

Underlining indicates amendments to bill.

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

Italics indicate opposite chamber / conference committee amendments.



1 telephone number with the prescription drug dispensed; requiring a pharmacy
 2 benefits manager or its agent to cancel and reverse a therapeutic interchange
 3 under certain circumstances; requiring a pharmacy benefits manager or its
 4 agent to take certain actions if a therapeutic interchange is reversed; requiring
 5 a pharmacy benefits manager to maintain a certain toll-free telephone number;
 6 requiring certain disclosures to comply with certain privacy standards;
 7 requiring a pharmacy benefits manager to establish certain policies and
 8 procedures; making certain provisions applicable to health maintenance
 9 organizations; ~~providing certain penalties;~~ defining certain terms; and generally
 10 relating to regulation of pharmacy benefits managers.

11 BY adding to
 12 Article – Insurance
 13 Section 15–1601 and 15–1602 to be under the new subtitle “Subtitle 16.
 14 Pharmacy Benefits Managers”
 15 Annotated Code of Maryland
 16 (2006 Replacement Volume and 2007 Supplement)

17 BY adding to
 18 Article – Health – General
 19 Section 19–706(ppp)
 20 Annotated Code of Maryland
 21 (2005 Replacement Volume and 2007 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 **SUBTITLE 16. PHARMACY BENEFITS MANAGERS.**

26 ~~**15-1601.**~~

27 ~~(A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE~~
 28 ~~MEANINGS INDICATED.~~

29 ~~(2) “BENEFICIARY” MEANS AN INDIVIDUAL ON WHOSE BEHALF A~~
 30 ~~PURCHASER ENTERS INTO AN AGREEMENT WITH A PHARMACY BENEFITS~~
 31 ~~MANAGER.~~

32 ~~(3) (i) “PHARMACY BENEFITS MANAGEMENT SERVICES”~~
 33 ~~MEANS THE ADMINISTRATION OR MANAGEMENT OF PRESCRIPTION DRUG~~
 34 ~~BENEFITS.~~

35 ~~(ii) “PHARMACY BENEFITS MANAGEMENT SERVICES”~~
 36 ~~INCLUDES:~~

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

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

4 ~~3. ADMINISTRATION OF PAYMENTS RELATED TO~~
5 ~~PRESCRIPTION DRUG CLAIMS; AND~~

6 ~~4. NEGOTIATING OR ENTERING INTO CONTRACTUAL~~
7 ~~ARRANGEMENTS WITH PHARMACY PROVIDERS.~~

8 ~~(4) “PHARMACY BENEFITS MANAGER” MEANS A PERSON THAT~~
9 ~~PERFORMS PHARMACY BENEFITS MANAGEMENT SERVICES.~~

10 ~~(5) (i) “PURCHASER” MEANS A PERSON THAT ENTERS INTO AN~~
11 ~~AGREEMENT WITH A PHARMACY BENEFITS MANAGER FOR THE PROVISION OF~~
12 ~~PHARMACY BENEFITS MANAGEMENT SERVICES.~~

13 ~~(ii) “PURCHASER” INCLUDES THE STATE.~~

14 ~~(b) THE PROVISIONS OF THIS SECTION DO NOT APPLY TO A MANAGED~~
15 ~~CARE ORGANIZATION AUTHORIZED BY TITLE 15, SUBTITLE 1 OF THE~~
16 ~~HEALTH GENERAL ARTICLE.~~

17 ~~(c) A PHARMACY BENEFITS MANAGER MAY NOT SUBSTITUTE ANOTHER~~
18 ~~PRESCRIPTION DRUG FOR THE CURRENTLY PRESCRIBED PRESCRIPTION DRUG~~
19 ~~UNLESS:~~

20 ~~(1) THE SUBSTITUTION IS MADE FOR MEDICAL REASONS THAT~~
21 ~~BENEFIT THE BENEFICIARY; OR~~

22 ~~(2) THE SUBSTITUTION RESULTS IN FINANCIAL SAVINGS AND~~
23 ~~BENEFITS TO THE PURCHASER.~~

24 ~~(d) IF A PRESCRIPTION DRUG SUBSTITUTION IS MADE UNDER THIS~~
25 ~~SECTION, THE PHARMACY BENEFITS MANAGER SHALL DISCLOSE TO THE~~
26 ~~PURCHASER ANY BENEFIT OR PAYMENT:~~

27 ~~(1) RELATED TO THE SUBSTITUTION; AND~~

28 ~~(2) RECEIVED IN ANY FORM BY THE PHARMACY BENEFITS~~
29 ~~MANAGER FROM A PHARMACEUTICAL MANUFACTURER OR OTHER PERSON.~~

1 ~~(E) EXCEPT AS PROVIDED IN SUBSECTIONS (G) AND (H) OF THIS~~
2 ~~SECTION, A PHARMACY BENEFITS MANAGER SHALL:~~

3 ~~(1) OBTAIN AUTHORIZATION FROM A PRESCRIBER TO~~
4 ~~SUBSTITUTE ANOTHER PRESCRIPTION DRUG FOR A CURRENTLY PRESCRIBED~~
5 ~~PRESCRIPTION DRUG; AND~~

6 ~~(2) DISCLOSE TO THE PRESCRIBER:~~

7 ~~(I) THE COST SAVINGS FOR THE PURCHASER, IF ANY, THAT~~
8 ~~RESULT FROM THE DRUG SUBSTITUTION;~~

9 ~~(II) THE DIFFERENCE, IF ANY, IN COPAYMENTS OR OTHER~~
10 ~~OUT-OF-POCKET COSTS PAID BY THE BENEFICIARY TO OBTAIN THE~~
11 ~~SUBSTITUTE DRUG;~~

12 ~~(III) THE EXISTENCE OF ADDITIONAL PAYMENTS RECEIVED~~
13 ~~BY THE PHARMACY BENEFITS MANAGER THAT ARE NOT REFLECTED IN THE~~
14 ~~COST SAVINGS TO THE PURCHASER;~~

15 ~~(IV) THE CIRCUMSTANCES, IF ANY, UNDER WHICH THE~~
16 ~~CURRENTLY PRESCRIBED DRUG WILL BE COVERED;~~

17 ~~(V) THE CIRCUMSTANCES, IF ANY, AND EXTENT TO WHICH~~
18 ~~HEALTH CARE COSTS RELATED TO THE DRUG SUBSTITUTION WILL BE~~
19 ~~COMPENSATED; AND~~

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

22 ~~(F) IF AUTHORIZATION IS GIVEN VERBALLY, A PHARMACY BENEFITS~~
23 ~~MANAGER SHALL RECORD THE NAME AND TITLE OF THE PRESCRIBER~~
24 ~~AUTHORIZING THE PRESCRIPTION DRUG SUBSTITUTION.~~

25 ~~(G) SUBSECTION (E) OF THIS SECTION DOES NOT APPLY IF THE~~
26 ~~SUBSTITUTION IS FROM A BRAND NAME DRUG TO A GENERIC DRUG, AND THE~~
27 ~~SUBSTITUTION IS MADE IN ACCORDANCE WITH § 12-504 OF THE HEALTH~~
28 ~~OCCUPATIONS ARTICLE.~~

29 ~~(H) SUBSECTION (E)(2) OF THIS SECTION DOES NOT APPLY IF:~~

30 ~~(1) THE CURRENTLY PRESCRIBED DRUG IS NO LONGER~~
31 ~~AVAILABLE IN THE MARKET; OR~~

1 ~~(2) THE SUBSTITUTION IS REQUIRED FOR COVERAGE REASONS~~
2 ~~BECAUSE THE PRESCRIBED DRUG IS NOT COVERED BY THE BENEFICIARY'S~~
3 ~~FORMULARY OR PLAN.~~

4 ~~(I) A PHARMACY BENEFITS MANAGER MAY NOT SUBSTITUTE ANOTHER~~
5 ~~PRESCRIPTION DRUG FOR A CURRENTLY PRESCRIBED PRESCRIPTION DRUG~~
6 ~~UNLESS THE PHARMACY BENEFITS MANAGER PROVIDES THE BENEFICIARY OR~~
7 ~~THE BENEFICIARY'S REPRESENTATIVE THE FOLLOWING:~~

8 ~~(1) UNLESS THE SUBSTITUTION WAS EXEMPTED UNDER~~
9 ~~SUBSECTION (G) OF THIS SECTION, A NOTIFICATION THAT:~~

10 ~~(I) THE PHARMACY BENEFITS MANAGER REQUESTED A~~
11 ~~DRUG SUBSTITUTION BY CONTACTING THE BENEFICIARY'S PRESCRIBER; AND~~

12 ~~(II) THE PRESCRIBER APPROVED THE DRUG SUBSTITUTION;~~

13 ~~(2) THE NAMES OF THE PROPOSED DRUG SUBSTITUTION AND THE~~
14 ~~CURRENTLY PRESCRIBED DRUG;~~

15 ~~(3) THE DIFFERENCE, IF ANY, IN COPAYMENTS OR OTHER~~
16 ~~OUT-OF-POCKET COSTS PAID BY THE BENEFICIARY TO OBTAIN THE~~
17 ~~SUBSTITUTE DRUG;~~

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

20 ~~(5) THE CIRCUMSTANCES, IF ANY, UNDER WHICH THE~~
21 ~~CURRENTLY PRESCRIBED DRUG WILL BE COVERED;~~

22 ~~(6) THE CIRCUMSTANCES, IF ANY, AND THE EXTENT TO WHICH~~
23 ~~HEALTH CARE COSTS RELATED TO THE DRUG SUBSTITUTION WILL BE~~
24 ~~COMPENSATED;~~

25 ~~(7) A NOTIFICATION THAT THE BENEFICIARY MAY DECLINE THE~~
26 ~~DRUG SUBSTITUTION IF THE CURRENTLY PRESCRIBED DRUG REMAINS ON THE~~
27 ~~BENEFICIARY'S FORMULARY, AND THE BENEFICIARY IS WILLING TO PAY ANY~~
28 ~~DIFFERENCE IN THE COPAYMENT AMOUNT; AND~~

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

31 ~~(J) (1) A PHARMACY BENEFITS MANAGER SHALL CANCEL AND~~
32 ~~REVERSE A PRESCRIPTION DRUG SUBSTITUTION ON WRITTEN OR VERBAL~~

1 ~~INSTRUCTIONS FROM A PRESCRIBER, THE BENEFICIARY, OR THE~~
2 ~~BENEFICIARY'S REPRESENTATIVE.~~

3 ~~(2) IF A PRESCRIBER, THE BENEFICIARY, OR THE BENEFICIARY'S~~
4 ~~REPRESENTATIVE CANCELS AND REVERSES A DRUG SUBSTITUTION, THE~~
5 ~~PHARMACY BENEFITS MANAGER SHALL:~~

6 ~~(I) OBTAIN A PRESCRIPTION FOR AND DISPENSE THE~~
7 ~~CURRENTLY PRESCRIBED DRUG;~~

8 ~~(II) CHARGE THE BENEFICIARY ONLY ONE COPAYMENT; AND~~

9 ~~(III) IF A BENEFICIARY WILL EXHAUST THE SUPPLY OF THE~~
10 ~~CURRENTLY PRESCRIBED DRUG BEFORE A REPLACEMENT SHIPMENT WILL~~
11 ~~ARRIVE TO THE BENEFICIARY, ARRANGE FOR DISPENSING OF AN APPROPRIATE~~
12 ~~QUANTITY OF REPLACEMENT DRUGS AT A RETAIL OR INSTITUTIONAL~~
13 ~~PHARMACY AT NO ADDITIONAL COST TO THE BENEFICIARY.~~

14 ~~(3) A PHARMACY BENEFITS MANAGER MAY NOT BE REQUIRED TO~~
15 ~~CANCEL AND REVERSE A DRUG SUBSTITUTION IF:~~

16 ~~(I) THE PRESCRIBED DRUG IS NO LONGER ON THE~~
17 ~~PURCHASER'S FORMULARY; OR~~

18 ~~(II) A BENEFICIARY IS UNWILLING TO PAY A HIGHER~~
19 ~~COPAYMENT OR OTHER COST ASSOCIATED WITH THE PRESCRIBED DRUG.~~

20 ~~(K) A PHARMACY BENEFITS MANAGER SHALL MAINTAIN A TOLL FREE~~
21 ~~TELEPHONE NUMBER 24 HOURS A DAY, 7 DAYS A WEEK, FOR PRESCRIBERS,~~
22 ~~PHARMACY PROVIDERS, AND BENEFICIARIES.~~

23 ~~(L) ALL DISCLOSURES MADE UNDER THIS SECTION SHALL COMPLY~~
24 ~~WITH THE PRIVACY STANDARDS OF THE FEDERAL HEALTH INSURANCE~~
25 ~~PORTABILITY AND ACCOUNTABILITY ACT.~~

26 ~~(M) ON OR BEFORE APRIL 1, 2009, THE COMMISSIONER SHALL ADOPT~~
27 ~~REGULATIONS TO IMPLEMENT THIS SECTION.~~

28 ~~(N) (1) THE COMMISSIONER MAY ASSESS A CIVIL PENALTY NOT~~
29 ~~EXCEEDING \$10,000 FOR EACH VIOLATION OF THIS SECTION.~~

30 ~~(2) IN ADDITION TO OR INSTEAD OF ASSESSING A CIVIL PENALTY,~~
31 ~~THE COMMISSIONER MAY REQUIRE THE PHARMACY BENEFITS MANAGER TO~~

1 ~~MAKE RESTITUTION TO ANY PERSON WHO HAS SUFFERED FINANCIAL INJURY~~
2 ~~BECAUSE OF THE VIOLATION OF THIS SECTION.~~

3 **15-1601.**

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

6 (B) **“AGENT” MEANS A PHARMACY, A PHARMACIST, A MAIL ORDER**
7 **PHARMACY, OR A NONRESIDENT PHARMACY ACTING ON BEHALF OR AT THE**
8 **DIRECTION OF A PHARMACY BENEFITS MANAGER.**

9 (C) **“BENEFICIARY” MEANS AN INDIVIDUAL WHO RECEIVES**
10 **PRESCRIPTION DRUG COVERAGE OR BENEFITS FROM A PURCHASER.**

11 (D) **“ERISA” HAS THE MEANING STATED IN § 8-301 OF THIS ARTICLE.**

12 (E) **“NONPROFIT HEALTH MAINTENANCE ORGANIZATION” HAS THE**
13 **MEANING STATED IN § 6-121(A) OF THIS ARTICLE.**

14 (F) **“NONRESIDENT PHARMACY” HAS THE MEANING STATED IN § 12-403**
15 **OF THE HEALTH OCCUPATIONS ARTICLE.**

16 (G) **“PHARMACIST” HAS THE MEANING STATED IN § 12-101 OF THE**
17 **HEALTH OCCUPATIONS ARTICLE.**

18 (H) **“PHARMACY” HAS THE MEANING STATED IN § 12-101 OF THE**
19 **HEALTH OCCUPATIONS ARTICLE.**

20 (I) (1) **“PHARMACY BENEFITS MANAGEMENT SERVICES” MEANS:**

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

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

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

28 1. **MAIL SERVICE PHARMACY;**

1 **2. CLAIMS PROCESSING, RETAIL NETWORK**
2 **MANAGEMENT, AND PAYMENT OF CLAIMS TO PHARMACIES FOR PRESCRIPTION**
3 **DRUGS DISPENSED TO BENEFICIARIES;**

4 **3. CLINICAL FORMULARY DEVELOPMENT AND**
5 **MANAGEMENT SERVICES;**

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

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

9 **6. DISEASE MANAGEMENT PROGRAMS.**

10 **(2) “PHARMACY BENEFITS MANAGEMENT SERVICES” DOES NOT**
11 **INCLUDE ANY SERVICE PROVIDED BY A NONPROFIT HEALTH MAINTENANCE**
12 **ORGANIZATION THAT OPERATES AS A GROUP MODEL, PROVIDED THAT THE**
13 **SERVICE:**

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

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

18 **(J) “PHARMACY BENEFITS MANAGER” MEANS A PERSON THAT**
19 **PERFORMS PHARMACY BENEFITS MANAGEMENT SERVICES.**

20 **(K) “PHARMACY AND THERAPEUTICS COMMITTEE” MEANS A**
21 **COMMITTEE ESTABLISHED BY A PHARMACY BENEFITS MANAGER TO:**

22 **(1) OBJECTIVELY APPRAISE AND EVALUATE PRESCRIPTION**
23 **DRUGS; AND**

24 **(2) MAKE RECOMMENDATIONS TO A PURCHASER REGARDING THE**
25 **SELECTION OF DRUGS FOR THE PURCHASER’S FORMULARY.**

26 **(L) (1) “PURCHASER” MEANS THE STATE EMPLOYEE AND RETIREE**
27 **HEALTH AND WELFARE BENEFITS PROGRAM, AN INSURER, A NONPROFIT**
28 **HEALTH SERVICE PLAN, OR A HEALTH MAINTENANCE ORGANIZATION THAT:**

29 **(I) PROVIDES PRESCRIPTION DRUG COVERAGE OR**
30 **BENEFITS IN THE STATE; AND**

1 (II) ENTERS INTO AN AGREEMENT WITH A PHARMACY
2 BENEFITS MANAGER FOR THE PROVISION OF PHARMACY BENEFITS
3 MANAGEMENT SERVICES.

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

9 (M) (1) "THERAPEUTIC INTERCHANGE" MEANS ANY CHANGE FROM
10 ONE PRESCRIPTION DRUG TO ANOTHER.

11 (2) "THERAPEUTIC INTERCHANGE" DOES NOT INCLUDE:

12 (I) A CHANGE INITIATED PURSUANT TO A DRUG
13 UTILIZATION REVIEW;

14 (II) A CHANGE INITIATED FOR PATIENT SAFETY REASONS;

15 (III) A CHANGE REQUIRED DUE TO MARKET UNAVAILABILITY
16 OF THE CURRENTLY PRESCRIBED DRUG;

17 (IV) A CHANGE FROM A BRAND NAME DRUG TO A GENERIC
18 DRUG IN ACCORDANCE WITH § 12-504 OF THE HEALTH OCCUPATIONS
19 ARTICLE; OR

20 (V) A CHANGE REQUIRED FOR COVERAGE REASONS
21 BECAUSE THE ORIGINALLY PRESCRIBED DRUG IS NOT COVERED BY THE
22 BENEFICIARY'S FORMULARY OR PLAN.

23 (N) "THERAPEUTIC INTERCHANGE SOLICITATION" MEANS ANY
24 COMMUNICATION BY A PHARMACY BENEFITS MANAGER FOR THE PURPOSE OF
25 REQUESTING A THERAPEUTIC INTERCHANGE.

26 15-1602.

27 (A) A PHARMACY BENEFITS MANAGER OR ITS AGENT MAY NOT REQUEST
28 A THERAPEUTIC INTERCHANGE UNLESS:

29 (1) THE PROPOSED THERAPEUTIC INTERCHANGE IS FOR
30 MEDICAL REASONS THAT BENEFIT THE BENEFICIARY; OR

1 **(2) THE PROPOSED THERAPEUTIC INTERCHANGE WILL RESULT IN**
2 **FINANCIAL SAVINGS AND BENEFITS TO THE PURCHASER OR THE BENEFICIARY.**

3 **(B) (1) BEFORE MAKING A THERAPEUTIC INTERCHANGE, A**
4 **PHARMACY BENEFITS MANAGER OR ITS AGENT SHALL OBTAIN AUTHORIZATION**
5 **FROM A PRESCRIBER OR AN INDIVIDUAL AUTHORIZED BY THE PRESCRIBER.**

6 **(C) IN ANY THERAPEUTIC INTERCHANGE SOLICITATION, THE**
7 **FOLLOWING SHALL BE DISCLOSED TO THE PRESCRIBER:**

8 **(1) THAT A THERAPEUTIC INTERCHANGE IS BEING SOLICITED;**

9 **(2) THE CIRCUMSTANCES UNDER WHICH THE ORIGINALLY**
10 **PRESCRIBED DRUG WILL BE COVERED BY THE PURCHASER;**

11 **(3) THE DIFFERENCE IN COPAYMENTS OR COINSURANCE TO BE**
12 **PAID BY THE BENEFICIARY TO OBTAIN THE PROPOSED DRUG;**

13 **(4) THE CIRCUMSTANCES AND EXTENT TO WHICH HEALTH CARE**
14 **COSTS RELATED TO THE THERAPEUTIC INTERCHANGE WILL BE COMPENSATED;**
15 **AND**

16 **(5) ANY CLINICALLY SIGNIFICANT DIFFERENCES, AS**
17 **DETERMINED BY A PHARMACY AND THERAPEUTICS COMMITTEE OF THE**
18 **PHARMACY BENEFITS MANAGER, WITH RESPECT TO EFFICACY, SIDE EFFECTS,**
19 **AND POTENTIAL IMPACT ON HEALTH AND SAFETY.**

20 **(D) WHEN SOLICITING A THERAPEUTIC INTERCHANGE FROM A**
21 **PRESCRIBER, A PHARMACY BENEFITS MANAGER OR ITS AGENT MAY NOT MAKE A**
22 **CLAIM THAT THE THERAPEUTIC INTERCHANGE WILL SAVE THE PURCHASER**
23 **MONEY UNLESS THE CLAIM CAN BE SUBSTANTIATED.**

24 **(E) IF THE PHARMACY BENEFITS MANAGER OR ITS AGENT RECEIVES**
25 **PAYMENT FOR MAKING A THERAPEUTIC INTERCHANGE FROM A**
26 **PHARMACEUTICAL MANUFACTURER OR OTHER PERSON, INCLUDING THE**
27 **PHARMACY BENEFITS MANAGER, THAT IS NOT REFLECTED IN COST SAVINGS TO**
28 **THE PURCHASER, THE EXISTENCE OF THE PAYMENT SHALL BE COMMUNICATED**
29 **TO THE PRESCRIBER AT THE TIME OF THE THERAPEUTIC INTERCHANGE**
30 **SOLICITATION.**

31 **(F) IF A THERAPEUTIC INTERCHANGE OCCURS, THE PHARMACY**
32 **BENEFITS MANAGER OR ITS AGENT SHALL:**

33 **(1) DISCLOSE TO THE BENEFICIARY, ORALLY OR IN WRITING:**

1 (I) THAT THE PHARMACY BENEFITS MANAGER OR ITS
2 AGENT REQUESTED A THERAPEUTIC INTERCHANGE BY CONTACTING THE
3 BENEFICIARY'S PRESCRIBER;

4 (II) THE PRESCRIBER APPROVED THE THERAPEUTIC
5 INTERCHANGE;

6 (III) THE NAMES OF THE ORIGINALLY PRESCRIBED DRUG
7 AND THE DRUG DISPENSED PURSUANT TO THE THERAPEUTIC INTERCHANGE;

8 (IV) THE DIFFERENCE IN COPAYMENTS OR COINSURANCE TO
9 BE PAID BY THE BENEFICIARY TO OBTAIN THE DRUG DISPENSED PURSUANT TO
10 THE THERAPEUTIC INTERCHANGE;

11 (V) THE CIRCUMSTANCES UNDER WHICH THE ORIGINALLY
12 PRESCRIBED DRUG WILL BE COVERED;

13 (VI) THE CIRCUMSTANCES UNDER AND THE EXTENT TO
14 WHICH HEALTH CARE COSTS RELATED TO THE THERAPEUTIC INTERCHANGE
15 WILL BE COMPENSATED; AND

16 (VII) THAT THE BENEFICIARY MAY DECLINE THE
17 THERAPEUTIC INTERCHANGE IF THE ORIGINALLY PRESCRIBED DRUG REMAINS
18 ON THE BENEFICIARY'S FORMULARY, AND THE BENEFICIARY IS WILLING TO PAY
19 ANY DIFFERENCE IN THE COPAYMENT OR COINSURANCE; AND

20 (2) INCLUDE WITH THE PRESCRIPTION DRUG DISPENSED:

21 (I) A PATIENT PACKAGE INSERT ABOUT POTENTIAL SIDE
22 EFFECTS; AND

23 (II) A TOLL-FREE TELEPHONE NUMBER TO COMMUNICATE
24 WITH THE PHARMACY BENEFITS MANAGER.

25 (G) (1) A PHARMACY BENEFITS MANAGER OR ITS AGENT SHALL
26 CANCEL AND REVERSE A THERAPEUTIC INTERCHANGE ON WRITTEN OR VERBAL
27 INSTRUCTIONS FROM A PRESCRIBER, THE BENEFICIARY, OR THE
28 BENEFICIARY'S REPRESENTATIVE.

29 (2) IF A THERAPEUTIC INTERCHANGE IS REVERSED, THE
30 PHARMACY BENEFITS MANAGER OR ITS AGENT SHALL:

1 (I) OBTAIN A PRESCRIPTION FOR AND DISPENSE THE
2 ORIGINALLY PRESCRIBED PRESCRIPTION DRUG; AND

3 (II) CHARGE THE BENEFICIARY NO MORE THAN ONE
4 COPAYMENT.

5 (3) IF THE THERAPEUTIC INTERCHANGE OCCURRED THROUGH A
6 MAIL ORDER PHARMACY AND A BENEFICIARY WILL EXHAUST AN EXISTING
7 SUPPLY OF THE ORIGINALLY PRESCRIBED PRESCRIPTION DRUG BEFORE A
8 REPLACEMENT SHIPMENT WILL ARRIVE TO THE BENEFICIARY, THE PHARMACY
9 BENEFITS MANAGER OR ITS AGENT SHALL ARRANGE FOR DISPENSING OF AN
10 APPROPRIATE QUANTITY OF REPLACEMENT PRESCRIPTION DRUGS AT A LOCAL
11 COMMUNITY PHARMACY AT NO ADDITIONAL COST TO THE BENEFICIARY.

12 (4) A PHARMACY BENEFITS MANAGER OR ITS AGENT MAY NOT BE
13 REQUIRED TO CANCEL AND REVERSE A THERAPEUTIC INTERCHANGE IF A
14 BENEFICIARY IS UNWILLING TO PAY A HIGHER COPAYMENT OR COINSURANCE
15 ASSOCIATED WITH THE ORIGINALLY PRESCRIBED PRESCRIPTION DRUG.

16 (H) (1) A PHARMACY BENEFITS MANAGER SHALL MAINTAIN A
17 TOLL-FREE TELEPHONE NUMBER MONDAY THROUGH SATURDAY FOR
18 PRESCRIBERS, PHARMACIES, PHARMACISTS, AND BENEFICIARIES TO REQUEST
19 INFORMATION REGARDING A THERAPEUTIC INTERCHANGE.

20 (2) THE TOLL-FREE TELEPHONE NUMBER SHALL BE ACCESSIBLE
21 FROM 8 A.M. UNTIL AT LEAST 8 P.M. EASTERN STANDARD TIME.

22 (I) ALL DISCLOSURES MADE UNDER THIS SECTION SHALL COMPLY
23 WITH THE PRIVACY STANDARDS SET FORTH IN STATE AND FEDERAL LAW.

24 (J) A PHARMACY BENEFITS MANAGER SHALL ESTABLISH APPROPRIATE
25 POLICIES AND PROCEDURES TO IMPLEMENT THE REQUIREMENTS OF THIS
26 SECTION.

27 ~~(K) (1) THE COMMISSIONER MAY ASSESS A CIVIL PENALTY NOT~~
28 ~~EXCEEDING \$10,000 FOR EACH VIOLATION OF THIS SECTION.~~

29 ~~(2) IN ADDITION TO OR INSTEAD OF ASSESSING A CIVIL PENALTY,~~
30 ~~THE COMMISSIONER MAY REQUIRE THE PHARMACY BENEFITS MANAGER TO~~
31 ~~MAKE RESTITUTION TO ANY PERSON THAT HAS SUFFERED FINANCIAL INJURY~~
32 ~~BECAUSE OF A VIOLATION OF THIS SECTION.~~

1 19-706.

2 (PPP) THE PROVISIONS OF TITLE 15, SUBTITLE 16 OF THE INSURANCE
3 ARTICLE APPLY TO HEALTH MAINTENANCE ORGANIZATIONS.

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

Approved:

Governor.

President of the Senate.

Speaker of the House of Delegates.