

# SENATE BILL 723

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8lr2240  
CF HB 343

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By: **Senators Klausmeier, Della, and Pugh**  
Introduced and read first time: February 1, 2008  
Assigned to: Finance

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## A BILL ENTITLED

1 AN ACT concerning

2 **Pharmacy Benefits Managers – Prescription Drug Substitution**

3 FOR the purpose of prohibiting a pharmacy benefits manager from substituting one  
4 prescription drug for the drug originally prescribed unless certain conditions are  
5 met; requiring a pharmacy benefits manager to disclose certain information to a  
6 purchaser if a drug substitution is made; requiring a pharmacy benefits  
7 manager to obtain a certain authorization to make a drug substitution and to  
8 make certain disclosures to a prescriber; providing for certain exceptions;  
9 prohibiting a pharmacy benefits manager from substituting a drug for a  
10 currently prescribed drug unless the pharmacy benefits manager provides a  
11 beneficiary or the beneficiary’s representative with certain information;  
12 requiring a pharmacy benefits manager to maintain a certain toll-free  
13 telephone number; providing certain penalties; defining certain terms; and  
14 generally relating to regulation of pharmacy benefits managers.

15 BY adding to

16 Article – Insurance

17 Section 15–1601 to be under the new subtitle “Subtitle 16. Pharmacy Benefits  
18 Managers”

19 Annotated Code of Maryland

20 (2006 Replacement Volume and 2007 Supplement)

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

23 **Article – Insurance**

24 **SUBTITLE 16. PHARMACY BENEFITS MANAGERS.**

25 **15–1601.**

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EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1           (A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE  
2 MEANINGS INDICATED.

3                   (2) “BENEFICIARY” MEANS AN INDIVIDUAL ON WHOSE BEHALF A  
4 PURCHASER ENTERS INTO AN AGREEMENT WITH A PHARMACY BENEFITS  
5 MANAGER.

6                   (3) (I) “PHARMACY BENEFITS MANAGEMENT SERVICES”  
7 MEANS THE ADMINISTRATION OR MANAGEMENT OF PRESCRIPTION DRUG  
8 BENEFITS.

9                               (II) “PHARMACY BENEFITS MANAGEMENT SERVICES”  
10 INCLUDES:

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

13                                       2. PROCESSING OF PRESCRIPTION DRUG CLAIMS;

14                                       3. ADMINISTRATION OF PAYMENTS RELATED TO  
15 PRESCRIPTION DRUG CLAIMS; AND

16                                       4. NEGOTIATING OR ENTERING INTO CONTRACTUAL  
17 ARRANGEMENTS WITH PHARMACY PROVIDERS.

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

20                   (5) (I) “PURCHASER” MEANS A PERSON THAT ENTERS INTO AN  
21 AGREEMENT WITH A PHARMACY BENEFITS MANAGER FOR THE PROVISION OF  
22 PHARMACY BENEFITS MANAGEMENT SERVICES.

23                               (II) “PURCHASER” INCLUDES THE STATE.

24           (B) THE PROVISIONS OF THIS SECTION DO NOT APPLY TO A MANAGED  
25 CARE ORGANIZATION AUTHORIZED BY TITLE 15, SUBTITLE 1 OF THE  
26 HEALTH – GENERAL ARTICLE.

27           (C) A PHARMACY BENEFITS MANAGER MAY NOT SUBSTITUTE ANOTHER  
28 PRESCRIPTION DRUG FOR THE CURRENTLY PRESCRIBED PRESCRIPTION DRUG  
29 UNLESS:

30                   (1) THE SUBSTITUTION IS MADE FOR MEDICAL REASONS THAT  
31 BENEFIT THE BENEFICIARY; OR

1           **(2) THE SUBSTITUTION RESULTS IN FINANCIAL SAVINGS AND**  
2 **BENEFITS TO THE PURCHASER.**

3           **(D) IF A PRESCRIPTION DRUG SUBSTITUTION IS MADE UNDER THIS**  
4 **SECTION, THE PHARMACY BENEFITS MANAGER SHALL DISCLOSE TO THE**  
5 **PURCHASER ANY BENEFIT OR PAYMENT:**

6           **(1) RELATED TO THE SUBSTITUTION; AND**

7           **(2) RECEIVED IN ANY FORM BY THE PHARMACY BENEFITS**  
8 **MANAGER FROM A PHARMACEUTICAL MANUFACTURER OR OTHER PERSON.**

9           **(E) EXCEPT AS PROVIDED IN SUBSECTIONS (G) AND (H) OF THIS**  
10 **SECTION, A PHARMACY BENEFITS MANAGER SHALL:**

11           **(1) OBTAIN AUTHORIZATION FROM A PRESCRIBER TO**  
12 **SUBSTITUTE ANOTHER PRESCRIPTION DRUG FOR A CURRENTLY PRESCRIBED**  
13 **PRESCRIPTION DRUG; AND**

14           **(2) DISCLOSE TO THE PRESCRIBER:**

15           **(I) THE COST SAVINGS FOR THE PURCHASER, IF ANY, THAT**  
16 **RESULT FROM THE DRUG SUBSTITUTION;**

17           **(II) THE DIFFERENCE, IF ANY, IN COPAYMENTS OR OTHER**  
18 **OUT-OF-POCKET COSTS PAID BY THE BENEFICIARY TO OBTAIN THE**  
19 **SUBSTITUTE DRUG;**

20           **(III) THE EXISTENCE OF ADDITIONAL PAYMENTS RECEIVED**  
21 **BY THE PHARMACY BENEFITS MANAGER THAT ARE NOT REFLECTED IN THE**  
22 **COST SAVINGS TO THE PURCHASER;**

23           **(IV) THE CIRCUMSTANCES, IF ANY, UNDER WHICH THE**  
24 **CURRENTLY PRESCRIBED DRUG WILL BE COVERED;**

25           **(V) THE CIRCUMSTANCES, IF ANY, AND EXTENT TO WHICH**  
26 **HEALTH CARE COSTS RELATED TO THE DRUG SUBSTITUTION WILL BE**  
27 **COMPENSATED; AND**

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

1           **(F) IF AUTHORIZATION IS GIVEN VERBALLY, A PHARMACY BENEFITS**  
2 **MANAGER SHALL RECORD THE NAME AND TITLE OF THE PRESCRIBER**  
3 **AUTHORIZING THE PRESCRIPTION DRUG SUBSTITUTION.**

4           **(G) SUBSECTION (E) OF THIS SECTION DOES NOT APPLY IF THE**  
5 **SUBSTITUTION IS FROM A BRAND NAME DRUG TO A GENERIC DRUG, AND THE**  
6 **SUBSTITUTION IS MADE IN ACCORDANCE WITH § 12-504 OF THE HEALTH**  
7 **OCCUPATIONS ARTICLE.**

8           **(H) SUBSECTION (E)(2) OF THIS SECTION DOES NOT APPLY IF:**

9                   **(1) THE CURRENTLY PRESCRIBED DRUG IS NO LONGER**  
10 **AVAILABLE IN THE MARKET; OR**

11                   **(2) THE SUBSTITUTION IS REQUIRED FOR COVERAGE REASONS**  
12 **BECAUSE THE PRESCRIBED DRUG IS NOT COVERED BY THE BENEFICIARY'S**  
13 **FORMULARY OR PLAN.**

14           **(I) A PHARMACY BENEFITS MANAGER MAY NOT SUBSTITUTE ANOTHER**  
15 **PRESCRIPTION DRUG FOR A CURRENTLY PRESCRIBED PRESCRIPTION DRUG**  
16 **UNLESS THE PHARMACY BENEFITS MANAGER PROVIDES THE BENEFICIARY OR**  
17 **THE BENEFICIARY'S REPRESENTATIVE THE FOLLOWING:**

18                   **(1) UNLESS THE SUBSTITUTION WAS EXEMPTED UNDER**  
19 **SUBSECTION (G) OF THIS SECTION, A NOTIFICATION THAT:**

20                           **(I) THE PHARMACY BENEFITS MANAGER REQUESTED A**  
21 **DRUG SUBSTITUTION BY CONTACTING THE BENEFICIARY'S PRESCRIBER; AND**

22                           **(II) THE PRESCRIBER APPROVED THE DRUG SUBSTITUTION;**

23                           **(2) THE NAMES OF THE PROPOSED DRUG SUBSTITUTION AND THE**  
24 **CURRENTLY PRESCRIBED DRUG;**

25                           **(3) THE DIFFERENCE, IF ANY, IN COPAYMENTS OR OTHER**  
26 **OUT-OF-POCKET COSTS PAID BY THE BENEFICIARY TO OBTAIN THE**  
27 **SUBSTITUTE DRUG;**

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

30                           **(5) THE CIRCUMSTANCES, IF ANY, UNDER WHICH THE**  
31 **CURRENTLY PRESCRIBED DRUG WILL BE COVERED;**

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

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

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

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

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

17                   **(I) OBTAIN A PRESCRIPTION FOR AND DISPENSE THE**  
18 **CURRENTLY PRESCRIBED DRUG;**

19                   **(II) CHARGE THE BENEFICIARY ONLY ONE COPAYMENT; AND**

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

25           **(3) A PHARMACY BENEFITS MANAGER MAY NOT BE REQUIRED TO**  
26 **CANCEL AND REVERSE A DRUG SUBSTITUTION IF:**

27                   **(I) THE PRESCRIBED DRUG IS NO LONGER ON THE**  
28 **PURCHASER'S FORMULARY; OR**

29                   **(II) A BENEFICIARY IS UNWILLING TO PAY A HIGHER**  
30 **COPAYMENT OR OTHER COST ASSOCIATED WITH THE PRESCRIBED DRUG.**

31          **(K) A PHARMACY BENEFITS MANAGER SHALL MAINTAIN A TOLL-FREE**  
32 **TELEPHONE NUMBER 24 HOURS A DAY, 7 DAYS A WEEK, FOR PRESCRIBERS,**  
33 **PHARMACY PROVIDERS, AND BENEFICIARIES.**

1           (L) ALL DISCLOSURES MADE UNDER THIS SECTION SHALL COMPLY  
2 WITH THE PRIVACY STANDARDS OF THE FEDERAL HEALTH INSURANCE  
3 PORTABILITY AND ACCOUNTABILITY ACT.

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

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

8                   (2) IN ADDITION TO OR INSTEAD OF ASSESSING A CIVIL PENALTY,  
9 THE COMMISSIONER MAY REQUIRE THE PHARMACY BENEFITS MANAGER TO  
10 MAKE RESTITUTION TO ANY PERSON WHO HAS SUFFERED FINANCIAL INJURY  
11 BECAUSE OF THE VIOLATION OF THIS SECTION.

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