

# HOUSE BILL 343

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By: **Delegates Kipke, Beitzel, Benson, Bromwell, Costa, Elliott, George, Hammen, Heller, Holmes, Hubbard, Kach, King, Kullen, Love, McDonough, Pena-Melnyk, Reznik, Riley, Robinson, Sophocleus, and Weldon**

Introduced and read first time: January 25, 2008

Assigned to: Health and Government Operations

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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.**

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EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 **15-1601.**

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

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

7 (3) (I) "PHARMACY BENEFITS MANAGEMENT SERVICES"  
8 MEANS THE ADMINISTRATION OR MANAGEMENT OF PRESCRIPTION DRUG  
9 BENEFITS.

10 (II) "PHARMACY BENEFITS MANAGEMENT SERVICES"  
11 INCLUDES:

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

14 2. PROCESSING OF PRESCRIPTION DRUG CLAIMS;

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

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

19 (4) "PHARMACY BENEFITS MANAGER" MEANS A PERSON THAT  
20 PERFORMS PHARMACY BENEFITS MANAGEMENT SERVICES.

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

24 (II) "PURCHASER" INCLUDES THE STATE.

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

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

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

3           (2) THE SUBSTITUTION RESULTS IN FINANCIAL SAVINGS AND  
4 BENEFITS TO THE PURCHASER.

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

8           (1) RELATED TO THE SUBSTITUTION; AND

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

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

13           (1) OBTAIN AUTHORIZATION FROM A PRESCRIBER TO  
14 SUBSTITUTE ANOTHER PRESCRIPTION DRUG FOR A CURRENTLY PRESCRIBED  
15 PRESCRIPTION DRUG; AND

16           (2) DISCLOSE TO THE PRESCRIBER:

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

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

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

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

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

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

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

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

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

11                   (1) THE CURRENTLY PRESCRIBED DRUG IS NO LONGER  
12 AVAILABLE IN THE MARKET; OR

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

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

20                   (1) UNLESS THE SUBSTITUTION WAS EXEMPTED UNDER  
21 SUBSECTION (G) OF THIS SECTION, A NOTIFICATION THAT:

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

24                           (II) THE PRESCRIBER APPROVED THE DRUG SUBSTITUTION;

25                   (2) THE NAMES OF THE PROPOSED DRUG SUBSTITUTION AND THE  
26 CURRENTLY PRESCRIBED DRUG;

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

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

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

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

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

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

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

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

19           (I) OBTAIN A PRESCRIPTION FOR AND DISPENSE THE  
20 CURRENTLY PRESCRIBED DRUG;

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

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

27          (3) A PHARMACY BENEFITS MANAGER MAY NOT BE REQUIRED TO  
28 CANCEL AND REVERSE A DRUG SUBSTITUTION IF:

29           (I) THE PRESCRIBED DRUG IS NO LONGER ON THE  
30 PURCHASER'S FORMULARY; OR

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

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

4           **(L) ALL DISCLOSURES MADE UNDER THIS SECTION SHALL COMPLY**  
5 **WITH THE PRIVACY STANDARDS OF THE FEDERAL HEALTH INSURANCE**  
6 **PORTABILITY AND ACCOUNTABILITY ACT.**

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

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

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

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