SB0723/927171/1

BY: Finance Committee

AMENDMENTS TO SENATE BILL 723
(First Reading File Bill)

AMENDMENT NO. 1

On page 1, in line 2, strike "Prescription Drug Substitution" and substitute "Therapeutic Interchanges"; strike beginning with "from substituting" in line 3 down through "prescribed" in line 4 and substitute "or its agent from requesting a therapeutic interchange"; strike beginning with "requiring" in line 5 down through the semicolon in line 6; in line 7, after "manager" insert "or its agent"; in the same line, strike "drug substitution" and substitute "therapeutic interchange"; strike beginning with "providing" in line 8 down through "information" in line 11 and substitute "requiring a pharmacy benefits manager or its agent to disclose certain information to a beneficiary and include a certain insert and a certain telephone number with the prescription drug dispensed; requiring a pharmacy benefits manager or its agent to cancel and reverse a therapeutic interchange under certain circumstances; requiring a pharmacy benefits manager or its agent to take certain actions if a therapeutic interchange is reversed"; in line 13, after the first semicolon insert "requiring certain disclosures to comply with certain privacy standards; requiring a pharmacy benefits manager to establish certain policies and procedures; making certain provisions applicable to health maintenance organizations;"; in line 17, after "15–1601" insert "and 15–1602"; and after line 20, insert:

"BY adding to
Article – Health – General
Section 19–706(ppp)
Annotated Code of Maryland
(2005 Replacement Volume and 2007 Supplement)".

AMENDMENT NO. 2

(Over)

On pages 1 through 6, strike in their entirety the lines beginning with line 25 on page 1 through line 11 on page 6, inclusive, and substitute:

"**15–1601.**

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

(B) "AGENT" MEANS A PHARMACY, A PHARMACIST, A MAIL ORDER PHARMACY, OR A NONRESIDENT PHARMACY ACTING ON BEHALF OR AT THE DIRECTION OF A PHARMACY BENEFITS MANAGER.

(C) "BENEFICIARY" MEANS AN INDIVIDUAL WHO RECEIVES PRESCRIPTION DRUG COVERAGE OR BENEFITS FROM A PURCHASER.

(D) "ERISA" HAS THE MEANING STATED IN § 8-301 OF THIS ARTICLE.

(E) "NONPROFIT HEALTH MAINTENANCE ORGANIZATION" HAS THE MEANING STATED IN § 6–121(A) OF THIS ARTICLE.

(F) "NONRESIDENT PHARMACY" HAS THE MEANING STATED IN § 12-403 OF THE HEALTH OCCUPATIONS ARTICLE.

(G) "PHARMACIST" HAS THE MEANING STATED IN § 12-101 OF THE HEALTH OCCUPATIONS ARTICLE.

(H) "PHARMACY" HAS THE MEANING STATED IN § 12-101 OF THE HEALTH OCCUPATIONS ARTICLE.

(I) (1) "PHARMACY BENEFITS MANAGEMENT SERVICES" MEANS:

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

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

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

1. MAIL SERVICE PHARMACY;

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

3. CLINICAL FORMULARY DEVELOPMENT AND MANAGEMENT SERVICES;

4. REBATE CONTRACTING AND ADMINISTRATION;

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

6. DISEASE MANAGEMENT PROGRAMS.

(2) "PHARMACY BENEFITS MANAGEMENT SERVICES" DOES NOT INCLUDE ANY SERVICE PROVIDED BY A NONPROFIT HEALTH MAINTENANCE

ORGANIZATION THAT OPERATES AS A GROUP MODEL, PROVIDED THAT THE SERVICE:

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

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

(J) "PHARMACY BENEFITS MANAGER" MEANS A PERSON THAT PERFORMS PHARMACY BENEFITS MANAGEMENT SERVICES.

(K) "PHARMACY AND THERAPEUTICS COMMITTEE" MEANS A COMMITTEE ESTABLISHED BY A PHARMACY BENEFITS MANAGER TO:

(1) OBJECTIVELY APPRAISE AND EVALUATE PRESCRIPTION DRUGS; AND

(2) MAKE RECOMMENDATIONS TO A PURCHASER REGARDING THE SELECTION OF DRUGS FOR THE PURCHASER'S FORMULARY.

(L) (1) "PURCHASER" MEANS THE STATE EMPLOYEE AND RETIREE HEALTH AND WELFARE BENEFITS PROGRAM, AN INSURER, A NONPROFIT HEALTH SERVICE PLAN, OR A HEALTH MAINTENANCE ORGANIZATION THAT:

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

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

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

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

(2) "THERAPEUTIC INTERCHANGE" DOES NOT INCLUDE:

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

(II) A CHANGE INITIATED FOR PATIENT SAFETY REASONS;

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

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

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

(Over)

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

15-1602.

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

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

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

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

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

(1) THAT A THERAPEUTIC INTERCHANGE IS BEING SOLICITED;

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

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

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

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

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

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

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

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

(I) THAT THE PHARMACY BENEFITS MANAGER OR ITS AGENT REQUESTED A THERAPEUTIC INTERCHANGE BY CONTACTING THE

BENEFICIARY'S PRESCRIBER;

(II) THE PRESCRIBER APPROVED THE THERAPEUTIC INTERCHANGE;

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

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

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

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

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

(2) INCLUDE WITH THE PRESCRIPTION DRUG DISPENSED:

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

(II) A TOLL-FREE TELEPHONE NUMBER TO COMMUNICATE

WITH THE PHARMACY BENEFITS MANAGER.

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

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

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

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

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

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

(H) (1) A PHARMACY BENEFITS MANAGER SHALL MAINTAIN A TOLL-

FREE TELEPHONE NUMBER MONDAY THROUGH SATURDAY FOR PRESCRIBERS, PHARMACIES, PHARMACISTS, AND BENEFICIARIES TO REQUEST INFORMATION REGARDING A THERAPEUTIC INTERCHANGE.

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

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

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

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

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

Article – Health – General

19–706.

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