HB0580/946482/1

BY: Health and Government Operations Committee

AMENDMENTS TO HOUSE BILL 580

(First Reading File Bill)

AMENDMENT NO. 1

On page 1, in the sponsor line, strike "and Rudolph" and substitute "Rudolph, Benson, Bromwell, Donoghue, Kach, McDonough, Mizeur, Montgomery, Morhaim, Nathan–Pulliam, Pena–Melnyk, Pendergrass, Reznik, Riley, V. Turner, and Weldon"; in line 2, strike "Committee" and substitute "Committees"; in line 3, strike "members of"; in line 4, after "manager;" insert "requiring a pharmacy benefits manager to ensure that its pharmacy and therapeutics committee has certain policies and procedures; requiring a pharmacy benefits manager to disclose information about the composition of its pharmacy and therapeutics committee to a certain person under certain circumstances; prohibiting a pharmacy benefits manager from requiring a pharmacist to participate on its pharmacy and therapeutics committee;"; and in line 10, after "15–1601" insert "and 15–1602".

AMENDMENT NO. 2

On pages 1 through 3, strike in their entirety the lines beginning with line 23 on page 1 through line 22 on page 3, inclusive, and substitute:

"<u>15–1601.</u>

- (A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS INDICATED.
- (B) "BENEFICIARY" MEANS AN INDIVIDUAL WHO RECEIVES PRESCRIPTION DRUG COVERAGE OR BENEFITS FROM A PURCHASER.
 - (C) "ERISA" HAS THE MEANING STATED IN § 8–301 OF THIS ARTICLE.

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- (D) "FORMULARY" MEANS A LIST OF PRESCRIPTION DRUGS USED BY A PURCHASER.
- (E) "NONPROFIT HEALTH MAINTENANCE ORGANIZATION" HAS THE MEANING STATED IN § 6–121(A) OF THIS ARTICLE.
 - (F) (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. <u>CLAIMS PROCESSING, RETAIL NETWORK</u>

 MANAGEMENT AND PAYMENT OF CLAIMS TO PHARMACIES FOR PRESCRIPTION

 DRUGS DISPENSED TO BENEFICIARIES;
- 3. <u>CLINICAL FORMULARY DEVELOPMENT AND</u>
 MANAGEMENT SERVICES;
 - 4. REBATE CONTRACTING AND ADMINISTRATION;

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- 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.
- (G) "PHARMACY BENEFITS MANAGER" MEANS A PERSON THAT PERFORMS PHARMACY BENEFITS MANAGEMENT SERVICES.
- (H) "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.

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- (I) (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 ASSOCIATION AS DEFINED IN § 514(B)(6)(A)(II) OF ERISA.

15–1602.

- (A) A PHARMACY AND THERAPEUTICS COMMITTEE ESTABLISHED BY A PHARMACY BENEFITS MANAGER SHALL MEET THE REQUIREMENTS OF THIS SECTION.
 - (B) (1) A PHARMACY AND THERAPEUTICS COMMITTEE SHALL:
- (I) INCLUDE CLINICAL SPECIALISTS THAT REPRESENT THE NEEDS OF A PURCHASER'S BENEFICIARIES; AND

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- (II)INCLUDE AT LEAST ONE PRACTICING PHARMACIST AND ONE PRACTICING PHYSICIAN WHO ARE INDEPENDENT OF ANY DEVELOPER OR MANUFACTURER OF PRESCRIPTION DRUGS.

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- **(2)** EACH MEMBER OF A PHARMACY AND THERAPEUTICS COMMITTEE SHALL SIGN A CONFLICT OF INTEREST STATEMENT UPDATED AT LEAST ANNUALLY DISCLOSING ANY ECONOMIC INTEREST OR RELATIONSHIP THAT COULD INFLUENCE THE PHARMACY AND THERAPEUTICS COMMITTEE'S **DECISIONS.**
- **(3)** A MAJORITY OF THE MEMBERS OF A PHARMACY AND THERAPEUTICS COMMITTEE SHALL BE PRACTICING PHYSICIANS \mathbf{OR} PRACTICING PHARMACISTS.
- **(C)** A PHARMACY BENEFITS MANAGER SHALL ENSURE THAT ITS PHARMACY AND THERAPEUTICS COMMITTEE HAS:
- **(1)** POLICIES AND PROCEDURES, INCLUDING DISCLOSURE REQUIREMENTS, TO ADDRESS POTENTIAL CONFLICTS OF INTEREST THAT MEMBERS OF THE PHARMACY AND THERAPEUTICS COMMITTEE MAY HAVE WITH **DEVELOPERS OR MANUFACTURERS OF PRESCRIPTION DRUGS:**
- **(2)** A PROCESS TO EVALUATE MEDICAL AND SCIENTIFIC EVIDENCE CONCERNING THE SAFETY AND EFFECTIVENESS OF PRESCRIPTION DRUGS, INCLUDING AVAILABLE COMPARATIVE INFORMATION ON CLINICALLY SIMILAR PRESCRIPTION DRUGS, WHEN DECIDING WHAT PRESCRIPTION DRUGS TO RECOMMEND TO INCLUDE ON A FORMULARY;
- **(3)** A PROCESS TO EVALUATE MEDICAL AND SCIENTIFIC EVIDENCE CONCERNING THE SAFETY AND EFFECTIVENESS OF PRESCRIPTION

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DRUGS WHEN RECOMMENDING UTILIZATION REVIEW REQUIREMENTS, DOSE RESTRICTIONS, AND STEP THERAPY REQUIREMENTS; AND

- (4) A PROCESS TO ENABLE THE PHARMACY AND THERAPEUTICS
 COMMITTEE TO CONSIDER THE NEED TO RECOMMEND A FORMULARY CHANGE
 TO A PURCHASER IN A TIMELY MANNER BUT AT LEAST ANNUALLY.
- (D) THE COMMISSIONER MAY CONSIDER A PHARMACY AND THERAPEUTICS COMMITTEE OF A PHARMACY BENEFITS MANAGER AS HAVING MET THE REQUIREMENTS OF SUBSECTIONS (B) AND (C) OF THIS SECTION IF THE PHARMACY BENEFITS MANAGER HAS OBTAINED ACCREDITATION FROM AN ACCREDITING ORGANIZATION APPROVED BY THE COMMISSIONER.
- (E) ON REQUEST OF A PURCHASER FOR WHICH THE PHARMACY AND THERAPEUTICS COMMITTEE MAKES RECOMMENDATIONS, A PHARMACY BENEFITS MANAGER SHALL DISCLOSE INFORMATION ABOUT THE COMPOSITION OF ITS PHARMACY AND THERAPEUTICS COMMITTEE TO THE PURCHASER.
- (F) A PHARMACY BENEFITS MANAGER MAY NOT REQUIRE A PHARMACIST TO PARTICIPATE ON ITS PHARMACY AND THERAPEUTICS COMMITTEE."