

BY: Health and Government Operations Committee

AMENDMENTS TO HOUSE BILL NO. 1058

(First Reading File Bill)

AMENDMENT NO. 1

On page 1, in the sponsor line, strike “and Bromwell” and substitute “Bromwell, Benson, Boutin, Donoghue, Frank, Hubbard, Kullen, Mandel, Morhaim, Murray, Nathan-Pulliam, Oaks, Pendergrass, V. Turner, and Weldon”; in line 2, strike “Benefit” and substitute “Benefits”; in line 3, strike “benefit” and substitute “benefits”; in the same line, strike “(“PBM”)”; and in lines 5 and 7, in each instance, strike “PBM” and substitute “pharmacy benefits manager”.

On pages 1 and 2, strike beginning with “requiring” in line 9 on page 1 down through the first semicolon in line 9 on page 2 and substitute “exempting certain managed care organizations, insurers, nonprofit health service plans, and health maintenance organizations, and affiliates, subsidiaries, or other related entities of certain insurers, nonprofit health service plans, and health maintenance organizations from certain provisions of this Act, under certain circumstances; requiring a person to register with the Maryland Insurance Commissioner before the person acts as or represents itself as a pharmacy benefits manager in the State; requiring an applicant for registration file an application on a certain form and pay to the Commissioner a certain fee; requiring the Commissioner to register certain applicants; providing for the expiration and renewal of a registration; prohibiting a pharmacy benefits manager from taking certain actions; authorizing the Commissioner to deny a registration to an applicant or refuse to renew, suspend, or revoke a registration under certain circumstances and subject to certain hearing provisions; authorizing the Commissioner, if a registration is suspended or revoked, to permit the continued operation of a pharmacy benefits manager, for a certain period of time and under certain circumstances; requiring a pharmacy benefits manager to register as a third party administrator or a private review agent under certain circumstances; prohibiting, with a certain exception, an insurer, nonprofit health service plan, or health maintenance organization from entering into an agreement with a pharmacy benefits manager that has not registered with the Commissioner; requiring the Commissioner to conduct a certain examination in accordance with certain provisions of law; requiring a pharmacy benefits manager to maintain certain books and records for a certain period and in accordance with certain”.

(Over)

standards; requiring the Commissioner to adopt certain regulations on or before a certain date; requiring a pharmacy benefits manager to disclose in writing certain information to a prospective purchaser and a purchaser; specifying the manner in which certain disclosures must be provided; providing that a pharmacy benefits manager need not make certain disclosures unless and until the prospective purchaser or the purchaser agrees in writing to maintain certain information as confidential; providing that certain agreements may include certain remedies and certain persons; requiring a contract executed by a pharmacy benefits manager for the provision of pharmacy benefits management services to include certain items; establishing certain requirements for members of a pharmacy and therapeutics committee; prohibiting a pharmacy benefits manager from substituting one prescription drug for the drug originally prescribed unless certain conditions are met; requiring a pharmacy benefits manager to disclose certain information to a purchaser if a drug substitution is made; requiring a pharmacy benefits manager to obtain a certain authorization to make a drug substitution and to make certain disclosures to a prescriber; providing for certain exceptions; prohibiting a pharmacy benefits manager from substituting a drug for a currently prescribed drug unless the pharmacy benefits manager provides a beneficiary or the beneficiary's representative with certain information; requiring a pharmacy benefits manager to maintain a certain toll-free telephone number; requiring a pharmacy benefits manager to enter into certain contracts with pharmacy providers under certain circumstances; specifying certain requirements of the contracts; requiring a pharmacy benefits manager to allow a beneficiary to obtain covered pharmacy services from a certain pharmacy provider and allow a certain pharmacy that can meet certain conditions to provide certain services; requiring certain disclosures to comply with certain privacy standards; providing certain penalties; altering the definition of a "nonresident pharmacy" to include a pharmacy benefits manager under certain provisions of law; requiring a nonresident pharmacy to meet certain requirements; making certain provisions of law applicable to health maintenance organizations; allowing a certain person to act as a pharmacy benefits manager without registering with the Maryland Insurance Commissioner under certain circumstances;".

On page 2, in line 10, strike "benefit" and substitute "benefits"; after line 10, insert:

"BY adding to
Article - Health - General
Section 19-706(ddd)
Annotated Code of Maryland
(2000 Replacement Volume and 2004 Supplement)";

in line 18, strike “15-1717” and substitute “15-1723”; in line 19, strike “Benefit” and substitute “Benefits”; and after line 21, insert:

“BY repealing and reenacting, with amendments,

Article - Health Occupations
Section 12-101(k) and 12-403(e) and (f)
Annotated Code of Maryland
(2000 Replacement Volume and 2004 Supplement)

BY repealing and reenacting, without amendments,

Article - Health Occupations
Section 12-403(a), (b)(17), (d), and (g)
Annotated Code of Maryland
(2000 Replacement Volume and 2004 Supplement)”.

AMENDMENT NO. 2

On page 2, after line 23, insert:

“Article - Health - General

19-706.

(DDD) THE PROVISIONS OF § 15-805 AND TITLE 15, SUBTITLE 17 OF THE INSURANCE ARTICLE SHALL APPLY TO HEALTH MAINTENANCE ORGANIZATIONS.”;

and in line 32, strike beginning with “BENEFIT” through “PBM” and substitute “BENEFITS MANAGER”.

On page 3, in lines 4, 7, 16, 19, 28, 31, and 35, in each instance, strike “PBM” and substitute “PHARMACY BENEFITS MANAGER”.

AMENDMENT NO. 3

(Over)

On page 4, in line 1, strike “BENEFIT” and substitute “BENEFITS”.

On pages 4 through 14, strike in their entirety the lines beginning with line 5 on page 4 through line 5 on page 14, inclusive, and substitute:

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

“(C) “EXTRAPOLATION AUDIT” MEANS AN AUDIT OF A SAMPLE OF PRESCRIPTION BENEFIT CLAIMS SUBMITTED BY A PHARMACY TO A PHARMACY BENEFITS MANAGER OR ITS DESIGNATED CONTRACTOR OR AGENT THAT IS USED TO ESTIMATE AUDIT RESULTS FOR A LARGER BATCH OR GROUP OF CLAIMS.

“(D) “LABELER” MEANS A PERSON THAT:

(1) RECEIVES PRESCRIPTION DRUGS FROM A MANUFACTURER OR WHOLESALER AND REPACKAGES THOSE DRUGS FOR LATER RETAIL SALE; AND

(2) HAS A LABELER CODE FROM THE FEDERAL FOOD AND DRUG ADMINISTRATION UNDER 21 CFR § 207.20.

“(E) (1) “PHARMACY BENEFITS MANAGEMENT SERVICES” MEANS THE ADMINISTRATION OR MANAGEMENT OF PRESCRIPTION DRUG BENEFITS.

(2) “PHARMACY BENEFITS MANAGEMENT SERVICES” INCLUDES:

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

(II) PROCESSING OF PRESCRIPTION DRUG CLAIMS;

(III) ADMINISTRATION OF PAYMENTS RELATED TO PRESCRIPTION DRUG CLAIMS; AND

(IV) NEGOTIATING OR ENTERING INTO CONTRACTUAL ARRANGEMENTS WITH PHARMACY PROVIDERS.

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

(G) "PHARMACY PROVIDER" MEANS A PHARMACY OR A PHARMACIST.

(H) "PROSPECTIVE PURCHASER" MEANS A PERSON TO WHICH A PHARMACY BENEFITS MANAGER OFFERS TO PROVIDE PHARMACY BENEFITS MANAGEMENT SERVICES.

(I) (1) "PURCHASER" MEANS A PERSON THAT ENTERS INTO AN AGREEMENT WITH A PHARMACY BENEFITS MANAGER FOR THE PROVISION OF PHARMACY BENEFITS MANAGEMENT SERVICES.

(2) "PURCHASER" INCLUDES THE STATE.

(J) "TRADE SECRET" HAS THE MEANING STATED IN § 11-1201 OF THE COMMERCIAL LAW ARTICLE.

(K) (1) "UTILIZATION REVIEW" HAS THE MEANING STATED IN § 15-10B-01 OF THIS TITLE.

(2) "UTILIZATION REVIEW" INCLUDES:

(I) DRUG UTILIZATION MANAGEMENT;

(II) DRUG UTILIZATION REVIEW SERVICES; AND

(III) STEP PROTOCOL THERAPY MANAGEMENT.

15-1702.

(Over)

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

(B) THE PROVISIONS OF §§ 15-1703 THROUGH 15-1717 OF THIS SUBTITLE DO NOT APPLY TO AN INSURER, NONPROFIT HEALTH SERVICE PLAN, OR HEALTH MAINTENANCE ORGANIZATION, OR AN AFFILIATE, SUBSIDIARY, OR OTHER RELATED ENTITY OF AN INSURER, NONPROFIT HEALTH SERVICE PLAN, OR HEALTH MAINTENANCE ORGANIZATION ACTING OR REPRESENTING ITSELF AS A PHARMACY BENEFITS MANAGER IF:

(1) THE INSURER, NONPROFIT HEALTH SERVICE PLAN, OR HEALTH MAINTENANCE ORGANIZATION OR THE AFFILIATE, SUBSIDIARY, OR OTHER RELATED ENTITY OF THE INSURER, NONPROFIT HEALTH SERVICE PLAN, OR HEALTH MAINTENANCE ORGANIZATION DIRECTLY OFFERS OR PROVIDES PHARMACY BENEFITS MANAGEMENT SERVICES; AND

(2) THE PHARMACY BENEFITS MANAGEMENT SERVICES ARE OFFERED OR PROVIDED ONLY TO ENROLLEES, SUBSCRIBERS, OR INSURED WHO ALSO ARE COVERED BY HEALTH BENEFITS OFFERED OR PROVIDED BY THE INSURER, NONPROFIT HEALTH SERVICE PLAN, OR HEALTH MAINTENANCE ORGANIZATION.

15-1703.

(A) A PERSON SHALL REGISTER WITH THE COMMISSIONER BEFORE THE PERSON ACTS AS OR REPRESENTS ITSELF AS A PHARMACY BENEFITS MANAGER IN THE STATE.

(B) AN APPLICANT FOR REGISTRATION SHALL:

(1) FILE WITH THE COMMISSIONER AN APPLICATION ON THE FORM THAT THE COMMISSIONER PROVIDES; AND

(2) PAY TO THE COMMISSIONER A REGISTRATION FEE SET BY THE COMMISSIONER.

(C) THE COMMISSIONER SHALL REGISTER EACH APPLICANT THAT MEETS THE REQUIREMENTS ESTABLISHED BY THE COMMISSIONER BY REGULATION.

15-1704.

(A) A REGISTRATION EXPIRES AT THE END OF EVERY OTHER JUNE 30, UNLESS IT IS RENEWED AS PROVIDED IN THIS SECTION.

(B) BEFORE A REGISTRATION EXPIRES, THE REGISTRANT MAY RENEW FOR AN ADDITIONAL 2-YEAR TERM, IF THE REGISTRANT:

(1) OTHERWISE IS ENTITLED TO BE REGISTERED;

(2) FILES WITH THE COMMISSIONER A RENEWAL APPLICATION ON THE FORM THE COMMISSIONER REQUIRES; AND

(3) PAYS TO THE COMMISSIONER A RENEWAL FEE AS SET BY THE COMMISSIONER.

(C) AN APPLICATION FOR RENEWAL OF A REGISTRATION SHALL BE CONSIDERED TIMELY IF POSTMARKED ON OR BEFORE JUNE 30 OF THE YEAR OF THE RENEWAL.

15-1705.

A PHARMACY BENEFITS MANAGER MAY NOT:

(1) VIOLATE ANY PROVISION OF THIS ARTICLE;

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- (2) VIOLATE ANY REGULATION ADOPTED UNDER THIS SUBTITLE;
- (3) KNOWINGLY FAIL TO COMPLY WITH AN ORDER OF THE COMMISSIONER;
- (4) FAIL TO MEET THE REQUIREMENTS FOR REGISTRATION ESTABLISHED BY THE COMMISSIONER UNDER § 15-1703(C) OF THIS SUBTITLE;
- (5) OBTAIN OR ATTEMPT TO OBTAIN A REGISTRATION BASED ON INACCURATE INFORMATION;
- (6) FRAUDULENTLY OR DECEPTIVELY OBTAIN OR USE A REGISTRATION;
- (7) FAIL TO PROTECT THE CONFIDENTIALITY OF MEDICAL RECORDS IN ACCORDANCE WITH APPLICABLE STATE AND FEDERAL LAWS; OR
- (8) ACT AS A PHARMACY BENEFITS MANAGER WITHOUT FIRST REGISTERING WITH THE COMMISSIONER.

15-1706.

(A) SUBJECT TO THE HEARING PROVISIONS OF TITLE 2 OF THIS ARTICLE, THE COMMISSIONER MAY DENY A REGISTRATION TO AN APPLICANT OR REFUSE TO RENEW, SUSPEND, OR REVOKE A REGISTRATION IF THE APPLICANT OR REGISTRANT VIOLATES ANY PROVISION OF § 15-1705 OF THIS SUBTITLE.

(B) IF THE REGISTRATION OF A PHARMACY BENEFITS MANAGER IS SUSPENDED OR REVOKED, THE COMMISSIONER, TO PROTECT THE INTERESTS OF BENEFICIARIES AND PHARMACY PROVIDERS, MAY PERMIT THE CONTINUED OPERATION OF THE PHARMACY BENEFITS MANAGER FOR A LIMITED PERIOD, NOT TO EXCEED 60 DAYS, UNDER CONDITIONS AND RESTRICTIONS DETERMINED BY THE COMMISSIONER.

15-1707.

(A) A PHARMACY BENEFITS MANAGER SHALL REGISTER WITH THE COMMISSIONER AS A THIRD PARTY ADMINISTRATOR UNDER TITLE 8, SUBTITLE 3 OF THIS ARTICLE IF THE PHARMACY BENEFITS MANAGER:

(1) PROCESSES PRESCRIPTION DRUG CLAIMS; OR

(2) ADMINISTERS PAYMENTS RELATED TO PRESCRIPTION DRUG CLAIMS.

(B) A PHARMACY BENEFITS MANAGER THAT PROCESSES PRESCRIPTION DRUG CLAIMS OR ADMINISTERS PAYMENTS RELATED TO PRESCRIPTION DRUG CLAIMS SHALL:

(1) PAY CLAIMS IN ACCORDANCE WITH § 15-1005 OF THIS TITLE; AND

(2) ADJUST CLAIMS IN ACCORDANCE WITH § 15-1008 OF THIS TITLE.

15-1708.

A PHARMACY BENEFITS MANAGER THAT CONDUCTS UTILIZATION REVIEW SHALL OBTAIN FROM THE COMMISSIONER A CERTIFICATE OF REGISTRATION AS A PRIVATE REVIEW AGENT UNDER SUBTITLE 10B OF THIS TITLE.

15-1709.

EXCEPT AS PROVIDED IN § 15-1702 OF THIS SUBTITLE, AN INSURER, NONPROFIT HEALTH SERVICE PLAN, OR HEALTH MAINTENANCE ORGANIZATION MAY NOT ENTER INTO AN AGREEMENT WITH A PHARMACY BENEFITS MANAGER THAT HAS NOT REGISTERED WITH THE COMMISSIONER.

15-1710.

(A) WHENEVER THE COMMISSIONER CONSIDERS IT ADVISABLE, THE COMMISSIONER SHALL EXAMINE THE AFFAIRS, TRANSACTIONS, ACCOUNTS, RECORDS, AND ASSETS OF EACH PHARMACY BENEFITS MANAGER.

(B) THE EXAMINATION SHALL BE CONDUCTED IN ACCORDANCE WITH § 2-207 OF THIS ARTICLE.

(C) THE EXPENSE OF THE EXAMINATION SHALL BE PAID IN ACCORDANCE WITH § 2-208 OF THIS ARTICLE.

(D) THE REPORTS OF THE EXAMINATION AND INVESTIGATION SHALL BE ISSUED IN ACCORDANCE WITH § 2-209 OF THIS ARTICLE.

15-1711.

A PHARMACY BENEFITS MANAGER SHALL MAINTAIN ADEQUATE BOOKS AND RECORDS ABOUT EACH PURCHASER FOR WHICH THE PHARMACY BENEFITS MANAGER PROVIDES PHARMACY BENEFITS MANAGEMENT SERVICES:

(1) IN ACCORDANCE WITH PRUDENT STANDARDS OF RECORD KEEPING;

(2) FOR THE DURATION OF THE AGREEMENT BETWEEN THE PHARMACY BENEFITS MANAGER AND THE PURCHASER; AND

(3) FOR 3 YEARS AFTER THE PHARMACY BENEFITS MANAGER CEASES TO PROVIDE PHARMACY BENEFITS MANAGEMENT SERVICES TO THE PURCHASER.

15-1712.

ON OR BEFORE APRIL 1, 2006, THE COMMISSIONER SHALL ADOPT REGULATIONS TO IMPLEMENT THIS SUBTITLE.

15-1713.

(A) A PHARMACY BENEFITS MANAGER SHALL DISCLOSE TO A PROSPECTIVE PURCHASER IN WRITING:

(1) THE AMOUNT OF ALL REBATES, ADMINISTRATIVE FEES, DETAILING PAYMENTS, EDUCATIONAL PAYMENTS, AND OTHER RETROSPECTIVE DISCOUNTS THAT THE PHARMACY BENEFITS MANAGER ESTIMATES IT WOULD RECEIVE, DIRECTLY OR INDIRECTLY, FROM PHARMACEUTICAL MANUFACTURERS OR LABELERS IN CONNECTION WITH PRESCRIPTION DRUG BENEFITS RELATED TO THE PROSPECTIVE PURCHASER, IF THE PROSPECTIVE PURCHASER WERE TO CONTRACT WITH THE PHARMACY BENEFITS MANAGER;

(2) THE NATURE, TYPE, AND AMOUNT OF ALL OTHER REVENUE THAT THE PHARMACY BENEFITS MANAGER ESTIMATES IT WOULD RECEIVE, DIRECTLY OR INDIRECTLY, FROM PHARMACEUTICAL MANUFACTURERS OR LABELERS IN CONNECTION WITH PRESCRIPTION DRUG BENEFITS RELATED TO THE PROSPECTIVE PURCHASER, IF THE PROSPECTIVE PURCHASER WERE TO CONTRACT WITH THE PHARMACY BENEFITS MANAGER;

(3) ANY ADMINISTRATIVE OR OTHER FEES THAT WOULD BE CHARGED BY THE PHARMACY BENEFITS MANAGER TO THE PROSPECTIVE PURCHASER;

(4) ANY ARRANGEMENTS WITH PRESCRIBING PROVIDERS, MEDICAL GROUPS, INDIVIDUAL PRACTICE ASSOCIATIONS, PHARMACY PROVIDERS, OR OTHER PERSONS THAT ARE ASSOCIATED WITH ACTIVITIES OF THE PHARMACY BENEFITS MANAGER TO ENCOURAGE FORMULARY COMPLIANCE OR OTHERWISE MANAGE PRESCRIPTION DRUG BENEFITS; AND

(5) A LIST OF ANY DRUGS THAT THE PHARMACY BENEFITS MANAGER, DIRECTLY OR INDIRECTLY, REPACKAGED AND ASSIGNED NEW OR DIFFERENT NATIONAL DRUG CODE NUMBERS INCLUDING, FOR EACH DRUG ON THE

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LIST:

(I) THE DRUG NAME AND STRENGTH;

(II) THE ORIGINAL NATIONAL DRUG CODE NUMBER AND THE
NEW NATIONAL DRUG CODE NUMBER; AND

(III) THE ORIGINAL PRICE AND THE NEW PRICE.

(B) THE DISCLOSURE REQUIRED UNDER SUBSECTION (A)(1) OF THIS
SECTION SHALL BE PROVIDED:

(1) IN THE AGGREGATE;

(2) FOR EACH THERAPEUTIC CLASS OF DRUGS ON A LIST OF
SPECIFIED THERAPEUTIC CLASSES; AND

(3) FOR FIVE INDIVIDUAL PRESCRIBED DRUGS IN EACH
THERAPEUTIC CLASS OF DRUGS AS REQUESTED BY THE PURCHASER.

(C) A THERAPEUTIC CLASS SHALL INCLUDE AT LEAST TWO DRUGS.

15-1714.

(A) AT LEAST QUARTERLY, A PHARMACY BENEFITS MANAGER SHALL
DISCLOSE TO A PURCHASER IN WRITING:

(1) THE AMOUNT OF ALL REBATES, ADMINISTRATIVE FEES,
DETAILING PAYMENTS, EDUCATIONAL PROGRAMS, AND OTHER RETROSPECTIVE
DISCOUNTS THAT THE PHARMACY BENEFITS MANAGER RECEIVES, DIRECTLY OR
INDIRECTLY, FROM PHARMACEUTICAL MANUFACTURERS OR LABELERS IN
CONNECTION WITH PRESCRIPTION DRUG BENEFITS SPECIFIC TO THE PURCHASER;

(2) THE NATURE, TYPE, AND AMOUNT OF ALL OTHER REVENUE
THAT THE PHARMACY BENEFITS MANAGER RECEIVES, DIRECTLY OR INDIRECTLY,

FROM PHARMACEUTICAL MANUFACTURERS OR LABELERS IN CONNECTION WITH PRESCRIPTION DRUG BENEFITS RELATED TO THE PURCHASER;

(3) ANY PRESCRIPTION DRUG UTILIZATION INFORMATION RELATED TO UTILIZATION BY THE PURCHASER'S BENEFICIARIES OR AGGREGATE UTILIZATION DATA THAT IS NOT SPECIFIC TO AN INDIVIDUAL BENEFICIARY, PRESCRIBER, OR PURCHASER;

(4) ANY ADMINISTRATIVE OR OTHER FEES CHARGED BY THE PHARMACY BENEFITS MANAGER TO THE PURCHASER;

(5) ANY ARRANGEMENTS WITH PRESCRIBING PROVIDERS, MEDICAL GROUPS, INDIVIDUAL PRACTICE ASSOCIATIONS, PHARMACY PROVIDERS, OR OTHER PERSONS THAT ARE ASSOCIATED WITH ACTIVITIES OF THE PHARMACY BENEFITS MANAGER TO ENCOURAGE FORMULARY COMPLIANCE OR OTHERWISE MANAGE PRESCRIPTION DRUG BENEFITS;

(6) A LIST OF ANY DRUGS THAT THE PHARMACY BENEFITS MANAGER, DIRECTLY OR INDIRECTLY, REPACKAGED AND ASSIGNED NEW OR DIFFERENT NATIONAL DRUG CODE NUMBERS INCLUDING, FOR EACH DRUG ON THE LIST:

(I) THE DRUG NAME AND STRENGTH;

(II) THE ORIGINAL NATIONAL DRUG CODE NUMBER AND THE NEW NATIONAL DRUG CODE NUMBER; AND

(III) THE ORIGINAL PRICE AND THE NEW PRICE; AND

(7) A LIST OF PRESCRIPTIONS FOR WHICH THERE WAS A DIFFERENCE BETWEEN THE PRICE PAID TO A RETAIL PHARMACY AND THE AMOUNT THAT WAS BILLED TO THE PURCHASER INCLUDING, FOR EACH PRESCRIPTION:

(I) THE PRESCRIPTION NUMBER;

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(II) THE DATE THE PRESCRIPTION WAS PROCESSED BY THE PHARMACY BENEFITS MANAGER;

(III) THE NATIONAL DRUG CODE NUMBER;

(IV) THE BENEFICIARY'S NAME; AND

(V) THE PRICE PAID TO THE RETAIL PHARMACY AND THE AMOUNT BILLED TO THE PURCHASER.

(B) THE DISCLOSURE REQUIRED UNDER SUBSECTION (A)(1) OF THIS SECTION SHALL BE PROVIDED:

(1) IN THE AGGREGATE;

(2) FOR EACH THERAPEUTIC CLASS OF DRUGS ON A LIST OF SPECIFIED THERAPEUTIC CLASSES; AND

(3) FOR FIVE INDIVIDUAL PRESCRIBED DRUGS IN EACH THERAPEUTIC CLASS OF DRUGS AS REQUESTED BY THE PURCHASER.

(C) A THERAPEUTIC CLASS SHALL INCLUDE AT LEAST TWO DRUGS.

15-1715.

(A) EXCEPT FOR UTILIZATION INFORMATION, AND EXCEPT AS PROVIDED IN SUBSECTION (D) OF THIS SECTION, A PHARMACY BENEFITS MANAGER NEED NOT MAKE THE DISCLOSURES REQUIRED UNDER §§ 15-1713 AND 15-1714 OF THIS SUBTITLE UNLESS AND UNTIL THE PROSPECTIVE PURCHASER OR THE PURCHASER AGREES IN WRITING TO MAINTAIN AS CONFIDENTIAL ANY PROPRIETARY INFORMATION DISCLOSED BY THE PHARMACY BENEFITS MANAGER.

(B) THE AGREEMENT UNDER SUBSECTION (A) OF THIS SECTION MAY:

(1) PROVIDE FOR EQUITABLE AND LEGAL REMEDIES IN THE EVENT OF A VIOLATION OF THE AGREEMENT; AND

(2) INCLUDE PERSONS WITH WHICH THE PROSPECTIVE PURCHASER OR PURCHASER CONTRACTS TO PROVIDE CONSULTING SERVICES RELATING TO PHARMACY BENEFITS MANAGEMENT SERVICES.

(C) PROPRIETARY INFORMATION INCLUDES:

(1) TRADE SECRETS; AND

(2) INFORMATION ABOUT PRICING, COSTS, REVENUES, TAXES, MARKET SHARE, NEGOTIATING STRATEGIES, CUSTOMERS, AND PERSONNEL HELD BY A PHARMACY BENEFITS MANAGER AND USED FOR ITS BUSINESS PURPOSES.

(D) THIS SECTION DOES NOT REDUCE THE AUTHORITY OF THE OFFICE OF THE ATTORNEY GENERAL OR THE COMMISSIONER TO OBTAIN INFORMATION AND USE THE INFORMATION IN ANY PROCEEDING.

15-1716.

A CONTRACT EXECUTED BY A PHARMACY BENEFITS MANAGER FOR THE PROVISION OF PHARMACY BENEFITS MANAGEMENT SERVICES SHALL INCLUDE:

(1) THE AMOUNT OF THE TOTAL REVENUES, REBATES, AND DISCOUNTS IDENTIFIED IN §§ 15-1713 AND 15-1714 OF THIS SUBTITLE THAT WILL BE PASSED ON TO THE PURCHASER;

(2) THE MAXIMUM ALLOWABLE COST AND AVERAGE WHOLESAL PRICE RESOURCES USED TO DETERMINE THE PRICE PAID TO A PHARMACY AND BILLED TO THE PURCHASER;

(3) THE CONDITIONS UNDER WHICH BENEFICIARY UTILIZATION DATA MAY BE DISCLOSED OR SOLD BY THE PHARMACY BENEFITS MANAGER TO

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ANY PERSON OTHER THAN THE PURCHASER;

(4) ANY ADMINISTRATIVE OR OTHER FEES:

(I) CHARGED BY THE PHARMACY BENEFITS MANAGER TO THE PURCHASER; OR

(II) COLLECTED BY THE PHARMACY BENEFITS MANAGER ON BEHALF OF THE PURCHASER;

(5) (I) THE CONDITIONS UNDER WHICH AN AUDIT WILL BE CONDUCTED OF THE CONTRACT FOR PHARMACY BENEFITS MANAGEMENT SERVICES;

(II) WHO WILL CONDUCT THE AUDIT; AND

(III) WHO WILL PAY FOR THE AUDIT;

(6) ANY REVENUES, REBATES, OR DISCOUNTS RECEIVED, DIRECTLY OR INDIRECTLY, BY THE PHARMACY BENEFITS MANAGER FROM PERSONS OTHER THAN PHARMACEUTICAL MANUFACTURERS AND LABELERS THAT ARE RELATED TO THE PHARMACY BENEFITS MANAGEMENT SERVICES TO BE PROVIDED TO THE PURCHASER;

(7) THE PROCESS FOR THE DEVELOPMENT OF FORMULARIES, NOTIFICATION OF CHANGES TO FORMULARIES, AND APPROVAL OF CHANGES BY THE PURCHASER; AND

(8) AN AGREEMENT TO PROVIDE TO THE PURCHASER A LIST OF PRESCRIPTIONS FOR WHICH THERE WAS A DIFFERENCE BETWEEN THE PRICE PAID TO A RETAIL PHARMACY AND THE AMOUNT THAT WILL BE OR WAS BILLED TO THE PURCHASER INCLUDING, FOR EACH PRESCRIPTION:

(I) THE PRESCRIPTION NUMBER;

(II) THE DATE THE PRESCRIPTION DRUG WAS PROCESSED BY THE PHARMACY BENEFITS MANAGER;

(III) THE NATIONAL DRUG CODE NUMBER;

(IV) THE BENEFICIARY'S NAME; AND

(V) THE PRICE PAID TO THE RETAIL PHARMACY AND THE AMOUNT BILLED TO THE PURCHASER.

15-1717.

(A) (1) EACH MEMBER OF A PHARMACY AND THERAPEUTICS COMMITTEE FOR A PHARMACY BENEFITS MANAGER SHALL BE:

(I) A PHYSICIAN OR OTHER AUTHORIZED PRESCRIBER, A PHARMACIST, OR A FACULTY MEMBER OF AN ACADEMIC MEDICAL CENTER; AND

(II) DISCLOSED BY NAME TO THE PURCHASER ON REQUEST.

(2) A MAJORITY OF COMMITTEE MEMBERS MAY NOT BE EMPLOYED BY THE PHARMACY BENEFITS MANAGER.

(B) A PHARMACY AND THERAPEUTICS COMMITTEE MEMBER MAY NOT:

(1) BE AN OFFICER, EMPLOYEE, DIRECTOR, OR AGENT OF A PHARMACEUTICAL MANUFACTURER; OR

(2) HAVE A FINANCIAL INTEREST IN A PHARMACEUTICAL MANUFACTURER, OTHER THAN OWNERSHIP OF A NOMINAL NUMBER OF SHARES OF THE PHARMACEUTICAL MANUFACTURER'S STOCK, PURCHASED ON A NATIONAL SECURITIES EXCHANGE.

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15-1718.

(A) A PHARMACY BENEFITS MANAGER MAY NOT SUBSTITUTE ANOTHER PRESCRIPTION DRUG FOR THE DRUG ORIGINALLY PRESCRIBED UNLESS:

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

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

(B) IF A PRESCRIPTION DRUG SUBSTITUTION IS MADE UNDER THIS SECTION, THE PHARMACY BENEFITS MANAGER SHALL DISCLOSE TO THE PURCHASER ANY BENEFIT OR PAYMENT RECEIVED IN ANY FORM BY THE PHARMACY BENEFITS MANAGER FROM A PHARMACEUTICAL MANUFACTURER OR OTHER PERSON RELATED TO THE SUBSTITUTION.

15-1719.

(A) EXCEPT AS PROVIDED IN SUBSECTION (C) OF THIS SECTION, A PHARMACY BENEFITS MANAGER SHALL:

(1) OBTAIN AUTHORIZATION FROM A PRESCRIBER TO SUBSTITUTE A PRESCRIPTION DRUG; AND

(2) DISCLOSE TO THE PRESCRIBER:

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

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

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

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

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

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

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

(C) A PHARMACY BENEFITS MANAGER MAY MAKE A PRESCRIPTION DRUG SUBSTITUTION WITHOUT OBTAINING AUTHORIZATION FROM A PRESCRIBER OR MAKING THE DISCLOSURES REQUIRED UNDER SUBSECTION (A) OF THIS SECTION IF:

(1) THE SUBSTITUTION IS FROM A BRAND NAME DRUG TO A GENERIC DRUG, AND THE SUBSTITUTION IS MADE IN ACCORDANCE WITH § 12-504 OF THE HEALTH OCCUPATIONS ARTICLE;

(2) THE CURRENTLY PRESCRIBED DRUG IS NO LONGER AVAILABLE IN THE MARKET; OR

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

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(D) A PHARMACY BENEFITS MANAGER MAY NOT SUBSTITUTE A PRESCRIPTION DRUG FOR A CURRENTLY PRESCRIBED PRESCRIPTION DRUG UNLESS THE PHARMACY BENEFITS MANAGER PROVIDES THE BENEFICIARY OR THE BENEFICIARY'S REPRESENTATIVE THE FOLLOWING:

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

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

(II) THE PRESCRIBER APPROVED THE DRUG SUBSTITUTION;

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

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

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

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

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

(7) A NOTIFICATION THAT THE BENEFICIARY MAY DECLINE THE DRUG SUBSTITUTION IF THE CURRENTLY PRESCRIBED DRUG REMAINS ON THE BENEFICIARY'S FORMULARY, AND THE BENEFICIARY IS WILLING TO PAY ANY

DIFFERENCE IN THE COPAYMENT AMOUNT; AND

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

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

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

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

(II) CHARGE THE BENEFICIARY ONLY ONE COPAYMENT; AND

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

(3) A PHARMACY BENEFITS MANAGER MAY NOT BE REQUIRED TO CANCEL AND REVERSE A DRUG SUBSTITUTION IF THE PRESCRIBED DRUG IS NO LONGER ON THE PURCHASER'S FORMULARY OR THE BENEFICIARY IS UNWILLING TO PAY A HIGHER COPAYMENT OR OTHER COST ASSOCIATED WITH THE PRESCRIBED DRUG.

(F) A PHARMACY BENEFITS MANAGER SHALL MAINTAIN A TOLL-FREE TELEPHONE NUMBER 24 HOURS A DAY, 7 DAYS A WEEK, FOR PRESCRIBERS,

(Over)

PHARMACY PROVIDERS, AND BENEFICIARIES.

15-1720.

(A) IF THE PHARMACY BENEFITS MANAGEMENT SERVICES PERFORMED BY A PHARMACY BENEFITS MANAGER FOR A PURCHASER INCLUDE NEGOTIATING OR ENTERING INTO CONTRACTUAL ARRANGEMENTS WITH PHARMACY PROVIDERS, BEFORE THE PHARMACY BENEFITS MANAGER MAY PROVIDE PHARMACY BENEFITS MANAGEMENT SERVICES FOR THE PURCHASER, THE PHARMACY BENEFITS MANAGER SHALL ENTER INTO ANY NECESSARY WRITTEN CONTRACTS WITH PHARMACY PROVIDERS.

(B) A WRITTEN CONTRACT SHALL REQUIRE THE PHARMACY BENEFITS MANAGER TO:

(1) DISCLOSE TO PHARMACY PROVIDERS:

(I) THE TERMS, CONDITIONS, FEES, BENEFIT DESIGNS, PROCESS, AND PROCEDURES FOR ACCESSING THE PHARMACY BENEFITS MANAGEMENT SERVICES PROVIDED BY THE PHARMACY BENEFITS MANAGER; AND

(II) THE PHARMACY BENEFITS MANAGER'S PROCEDURES FOR HANDLING DISPUTES;

(2) PROVIDE AT LEAST 30 DAYS' WRITTEN NOTICE TO PHARMACY PROVIDERS OF BENEFIT CHANGES, INCLUDING ADDITIONS OR DELETIONS TO COVERED PRESCRIPTION DRUGS, WITH THE EXCEPTION OF NEW DRUGS APPROVED BY THE U.S. FOOD AND DRUG ADMINISTRATION; AND

(3) STIPULATE THAT PHARMACY PROVIDERS WILL NOT BE REQUIRED TO AGREE TO EXTRAPOLATION AUDITS AS A CONDITION OF ENTERING INTO THE CONTRACT OR PARTICIPATING IN THE PHARMACY BENEFITS MANAGER'S NETWORK.

15-1721.

A PHARMACY BENEFITS MANAGER:

(1) SHALL ALLOW A BENEFICIARY TO OBTAIN COVERED PHARMACY SERVICES FROM THE PHARMACY PROVIDER OF THE BENEFICIARY'S CHOICE WITHIN THE PHARMACY BENEFITS MANAGER'S NETWORK;

(2) SHALL ALLOW A RETAIL OR INSTITUTIONAL PHARMACY THAT CAN MEET THE SAME TERMS AND CONDITIONS AS A MAIL ORDER PHARMACY TO PROVIDE THE SAME SERVICES PROVIDED BY A MAIL ORDER PHARMACY; AND

(3) MAY NOT:

(I) REQUIRE A BENEFICIARY TO OBTAIN PHARMACY SERVICES FROM A MAIL ORDER PHARMACY, IF A RETAIL OR INSTITUTIONAL PHARMACY CAN MEET THE SAME TERMS AND CONDITIONS AS A MAIL ORDER PHARMACY;

(II) USE ANY FINANCIAL OR OTHER DISINCENTIVES, PENALTIES, OR OTHER MEANS TO INFLUENCE, COERCE, OR STEER BENEFICIARIES AWAY FROM A RETAIL OR INSTITUTIONAL PHARMACY THAT CAN MEET THE SAME TERMS AND CONDITIONS AS A MAIL ORDER PHARMACY; OR

(III) LIMIT THE QUANTITY OF DRUGS THAT A BENEFICIARY MAY OBTAIN AT ANY ONE TIME FROM ANY TYPE OF PHARMACY PROVIDER, UNLESS THE LIMIT IS APPLIED UNIFORMLY TO ALL PHARMACY PROVIDERS THAT ARE WITHIN THE PHARMACY BENEFITS MANAGER'S NETWORK, UNDER CONTRACT, OR OTHERWISE AUTHORIZED TO PROVIDE PHARMACY SERVICES TO BENEFICIARIES.

15-1722.

ALL DISCLOSURES MADE UNDER THIS SUBTITLE SHALL COMPLY WITH THE PRIVACY STANDARDS OF THE FEDERAL HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT.

(Over)

15-1723.

IN ADDITION TO THE PENALTIES AUTHORIZED BY § 15-1706 OF THIS SUBTITLE, THE COMMISSIONER MAY ASSESS A CIVIL PENALTY NOT EXCEEDING \$10,000 AGAINST ANY PERSON THAT VIOLATES THIS SUBTITLE.

Article - Health Occupations

12-101.

(k) (1) “Nonresident pharmacy” means a pharmacy located outside this State that, in the normal course of business, as determined by the Board, ships, mails, or delivers drugs or devices to a person in this State pursuant to a prescription.

(2) “NONRESIDENT PHARMACY” INCLUDES A PHARMACY BENEFITS MANAGER, LOCATED WITHIN OR OUTSIDE THIS STATE, THAT IS REGULATED UNDER TITLE 15, SUBTITLE 17 OF THE INSURANCE ARTICLE, IF THE PHARMACY BENEFITS MANAGER SHIPS, MAILS, OR DELIVERS DRUGS OR DEVICES TO A PERSON IN THIS STATE PURSUANT TO A PRESCRIPTION.

12-403.

(a) This section does not require a nonresident pharmacy to violate the laws or regulations of the state in which it is located.

(b) Except as otherwise provided in this section, a pharmacy for which a pharmacy permit has been issued under this title:

(17) With regard to a prescription drug that is delivered in this State by the United States mail, a common carrier, or a delivery service and is not personally hand delivered directly to a patient or to the agent of the patient at the residence of the patient or at another location designated by the patient, shall:

(i) Provide a general written notice in each shipment of a prescription drug that alerts a consumer that, under certain circumstances, a medication's effectiveness may be affected by exposure to extremes of heat, cold, or humidity; and

(ii) Provide a specific written notice in each shipment of a prescription drug that provides a consumer with a toll-free or local consumer access telephone number accessible during regular hours of operation, which is designed to respond to consumer questions pertaining to medications; and

(d) A nonresident pharmacy shall hold a pharmacy permit issued by the Board.

(e) (1) In order to obtain a pharmacy permit from the Board, a nonresident pharmacy, TO THE EXTENT APPLICABLE, shall:

(i) Submit an application to the Board on the form that the Board requires;

(ii) Pay to the Board an application fee set by the Board;

(iii) Submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which the nonresident pharmacy is located; and

(iv) On the required permit application, identify the name and current address of an agent located in this State officially designated to accept service of process.

(2) A nonresident pharmacy shall report a change in the name or address of the resident agent in writing to the Board 30 days prior to the change.

(f) A nonresident pharmacy, TO THE EXTENT APPLICABLE, shall:

(1) Comply with the laws of the state in which it is located;

(2) On an annual basis and within 30 days after a change of office, corporate officer, or pharmacist, disclose to the Board the location, names, and titles of all principal corporate

officers and all pharmacists who are dispensing prescriptions for drugs or devices to persons in this State;

(3) Comply with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is located and all requests for information made by the Board pursuant to this section;

(4) Maintain at all times a valid, unexpired permit to conduct a pharmacy in compliance with the laws of the state in which it is located;

(5) Maintain its records of prescription drugs or devices dispensed to patients in this State so that the records are readily retrievable;

(6) During its regular hours of operation, but not less than 6 days a week, and for a minimum of 40 hours per week, provide toll-free telephone service to facilitate communication between patients in this State and a pharmacist who has access to the patient's prescription records;

(7) Disclose its toll-free telephone number on a label affixed to each container of drugs or devices;

(8) Comply with the laws of this State relating to the confidentiality of prescription records if there are no laws relating to the confidentiality of prescription records in the state in which the nonresident pharmacy is located; [and]

(9) Comply with the requirements of subsection (b)(17) of this section; AND

(10) REQUIRE EACH EMPLOYEE OR CONTRACTOR TO BE LICENSED TO PRACTICE PHARMACY IF THE EMPLOYEE OR CONTRACTOR PRACTICES PHARMACY FOR OR ON BEHALF OF THE NONRESIDENT PHARMACY.

(g) Subject to the hearing provisions of § 12-411 of this title, if a pharmacy or a nonresident pharmacy is operated in violation of this section, the Board may suspend the applicable pharmacy permit until the pharmacy complies with this section.”

AMENDMENT NO. 4

On page 14, after line 5, insert:

“SECTION 2. AND BE IT FURTHER ENACTED, That a person acting as a pharmacy benefits manager in the State on the effective date of this Act may continue to act as a pharmacy benefits manager in the State without being registered with the Maryland Insurance Commissioner, as required under Section 1 of this Act, if the person:

- (1) registers with the Commissioner on or before September 1, 2006; and
- (2) complies with all other applicable provisions of this Act.”;

and in line 6, strike “2.” and substitute “3.”.