J3 7lr0842

By: Delegates Rudolph and Elliott

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A BILL ENTITLED

1 AN ACT concerning

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Pharmacy Benefits Managers Regulation Act

FOR the purpose of prohibiting a pharmacy benefits manager from establishing the amount of a certain reimbursement on a certain basis; prohibiting a pharmacy benefits manager from imposing a certain copayment, deductible, limit on quantity, or other condition, under certain circumstances; requiring an insurance policy or contract or a pharmacy benefits manager to allow an insured or certificate holder to obtain pharmaceutical benefits from the pharmacy or pharmacist of the insured or certificate holder's choice, within any pharmacy network; 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 to 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, suspend, or revoke a registration or refuse to renew 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

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



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private review agent under certain circumstances; requiring a certain pharmacy benefits manager to pay and adjust claims according to certain statutory requirements; prohibiting 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 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; specifying provisions that apply to audits carried out by pharmacy benefits managers of pharmacies or pharmacy claims; 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 continue to act as a pharmacy benefits manager without registering with the Commissioner under

1 2	certain circumstances; defining certain terms; and generally relating to regulation of pharmacy benefits managers.
3 4 5 6 7	BY repealing and reenacting, with amendments, Article – Insurance Section 15–805 Annotated Code of Maryland (2006 Replacement Volume and 2006 Supplement)
8 9 10 11 12 13	BY adding to Article – Insurance Section 15–1601 through 15–1623 to be under the new subtitle "Subtitle 16. Pharmacy Benefits Managers" Annotated Code of Maryland (2006 Replacement Volume and 2006 Supplement)
14 15 16 17 18	BY adding to Article – Health – General Section 19–706(jjj) Annotated Code of Maryland (2005 Replacement Volume and 2006 Supplement)
19 20 21 22 23	BY repealing and reenacting, with amendments, Article – Health Occupations Section 12–101(m) and 12–403(e) and (f) Annotated Code of Maryland (2005 Replacement Volume and 2006 Supplement)
24 25 26 27 28	BY repealing and reenacting, without amendments, Article – Health Occupations Section 12–403(a), (b)(17), (d), and (g) Annotated Code of Maryland (2005 Replacement Volume and 2006 Supplement)
29 30	SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:
31	Article - Insurance
32	15–805.
33	(a) (1) In this section the following words have the meanings indicated.

1 2 3	(2) "Authorized prescriber" means a licensed dentist, licensed physician, or licensed podiatrist who is authorized under the Health Occupations Article to prescribe a pharmaceutical product.
4 5	(3) "Pharmaceutical product" means a drug or medicine that may be prescribed by an authorized prescriber.
6 7	(4) "Pharmacy benefits manager" has the meaning stated in \S 15–1601 of this title.
8 9	(b) This section does not apply to a policy or contract that is issued to an employer under a collective bargaining agreement.
10	(c) (1) This subsection applies to:
11 12 13	(I) each policy or contract that is issued or delivered in the State to an employer or individual by an insurer or nonprofit health service plan and that provides group or individual hospital, medical, or surgical benefits; AND
14 15 16	(II) EACH PHARMACY BENEFITS MANAGER THAT PROVIDES SERVICES, INCLUDING SERVICES PROVIDED AS AN AGENT OR CONTRACTOR, UNDER A POLICY OR CONTRACT UNDER ITEM (I) OF THIS PARAGRAPH.
17 18 19 20 21 22	(2) A policy [or], contract, OR PHARMACY BENEFITS MANAGER subject to this subsection that provides reimbursement for a pharmaceutical product prescribed by an authorized prescriber may not establish the amount of reimbursement to the insured or the insured's beneficiary, including copayments and deductibles, based on the identity, practicing specialty, or occupation of the authorized prescriber.
23	(d) (1) This subsection applies to:
24 25 26	(I) each individual or group policy or contract that is issued or delivered in the State to an employer or individual by an insurer or nonprofit health service plan and that provides benefits for pharmaceutical products; AND
27 28 29	(II) EACH PHARMACY BENEFITS MANAGER THAT PROVIDES SERVICES, INCLUDING SERVICES PROVIDED AS AN AGENT OR CONTRACTOR, UNDER A POLICY OR CONTRACT UNDER ITEM (I) OF THIS PARAGRAPH.

1	(2) A policy [or], contract, OR PHARMACY BENEFITS MANAGER
2	subject to this subsection may not impose a copayment, deductible, LIMIT ON
3	QUANTITY, or other condition on an insured or certificate holder who uses the services
4	of a community pharmacy that is not imposed when the insured or certificate holder
5	uses the services of a mail order pharmacy, if the benefits are provided under the same
6	program, policy, or contract.

(E) (1) THIS SUBSECTION APPLIES TO:

- 8 (I) EACH INDIVIDUAL OR GROUP POLICY OR CONTRACT
 9 THAT IS ISSUED OR DELIVERED IN THE STATE TO AN EMPLOYER OR INDIVIDUAL
 10 BY AN INSURER AND THAT PROVIDES BENEFITS FOR PHARMACEUTICAL
 11 PRODUCTS; AND
- 12 (II) EACH PHARMACY BENEFITS MANAGER THAT PROVIDES 13 SERVICES, INCLUDING SERVICES PROVIDED AS AN AGENT OR CONTRACTOR, 14 UNDER A POLICY OR CONTRACT UNDER ITEM (I) OF THIS PARAGRAPH.
- 15 (2) A POLICY, CONTRACT, OR PHARMACY BENEFITS MANAGER
 16 SUBJECT TO THIS SUBSECTION SHALL ALLOW AN INSURED OR CERTIFICATE
 17 HOLDER TO SELECT THE PHARMACY OR PHARMACIST OF THE INSURED OR
 18 CERTIFICATE HOLDER'S CHOICE FOR PHARMACEUTICAL BENEFITS, WITHIN ANY
 19 PHARMACY NETWORK ESTABLISHED UNDER OR BY THE POLICY, CONTRACT, OR
 20 PHARMACY BENEFITS MANAGER.
- 21 SUBTITLE 16. PHARMACY BENEFITS MANAGERS.
- 22 **15–1601.**

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- 23 (A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS 24 INDICATED.
- 25 **(B) "BENEFICIARY" MEANS AN INDIVIDUAL ON WHOSE BEHALF A**26 **PURCHASER ENTERS INTO AN AGREEMENT WITH A PHARMACY BENEFITS**27 **MANAGER.**
- 28 (C) "EXTRAPOLATION AUDIT" MEANS AN AUDIT OF A SAMPLE OF 29 PRESCRIPTION DRUG BENEFIT CLAIMS SUBMITTED BY A PHARMACY PROVIDER 30 TO A PHARMACY BENEFITS MANAGER OR ITS DESIGNATED CONTRACTOR OR

- 1 AGENT THAT IS USED TO ESTIMATE AUDIT RESULTS FOR A LARGER BATCH OR 2 GROUP OF CLAIMS.
- 3 (D) "LABELER" MEANS A PERSON THAT:
- 4 (1) RECEIVES PRESCRIPTION DRUGS FROM A MANUFACTURER OR 5 WHOLESALER AND REPACKAGES THOSE DRUGS FOR LATER RETAIL SALE; AND
- 6 (2) HAS A LABELER CODE FROM THE U.S. FOOD AND DRUG 7 ADMINISTRATION UNDER 21 CFR § 207.20.
- 8 (E) (1) "PHARMACY BENEFITS MANAGEMENT SERVICES" MEANS THE 9 ADMINISTRATION OR MANAGEMENT OF PRESCRIPTION DRUG BENEFITS.
- 10 (2) "PHARMACY BENEFITS MANAGEMENT SERVICES" INCLUDES:
- 11 (I) PROCUREMENT OF PRESCRIPTION DRUGS AT A
 12 NEGOTIATED RATE FOR DISPENSATION WITHIN THE STATE;
- 13 (II) PROCESSING OF PRESCRIPTION DRUG CLAIMS;
- 14 (III) ADMINISTRATION OF PAYMENTS RELATED TO 15 PRESCRIPTION DRUG CLAIMS; AND
- 16 (IV) NEGOTIATING OR ENTERING INTO CONTRACTUAL
 17 ARRANGEMENTS WITH PHARMACY PROVIDERS.
- 18 **(F) "PHARMACY BENEFITS MANAGER" MEANS A PERSON THAT**19 **PERFORMS PHARMACY BENEFITS MANAGEMENT SERVICES.**
- 20 (G) "PHARMACY PROVIDER" MEANS A PHARMACY OR A PHARMACIST.
- 21 (H) "PROSPECTIVE PURCHASER" MEANS A PERSON TO WHICH A 22 PHARMACY BENEFITS MANAGER OFFERS TO PROVIDE PHARMACY BENEFITS 23 MANAGEMENT SERVICES.
- 24 (I) (1) "PURCHASER" MEANS A PERSON THAT ENTERS INTO AN 25 AGREEMENT WITH A PHARMACY BENEFITS MANAGER FOR THE PROVISION OF
- 26 PHARMACY BENEFITS MANAGEMENT SERVICES.

1	(2) "PURCHASER" INCLUDES THE STATE.
2	(J) "TRADE SECRET" HAS THE MEANING STATED IN § 11-1201 OF THE
3	COMMERCIAL LAW ARTICLE.
4	(K) (1) "UTILIZATION REVIEW" HAS THE MEANING STATED IN
5	§ 15–10B–01 OF THIS TITLE.
6	(2) "UTILIZATION REVIEW" INCLUDES:
7	(I) DRUG UTILIZATION MANAGEMENT;
8	(II) DRUG UTILIZATION REVIEW SERVICES; AND
9	(III) STEP PROTOCOL THERAPY MANAGEMENT.
10	15–1602.
11	(A) THE PROVISIONS OF THIS SUBTITLE DO NOT APPLY TO A MANAGED
12	CARE ORGANIZATION AUTHORIZED BY TITLE 15, SUBTITLE 1 OF THE HEALTH -
13	GENERAL ARTICLE.
14	(B) THE PROVISIONS OF §§ 15–1603 THROUGH 15–1617 OF THIS
15	SUBTITLE DO NOT APPLY TO AN INSURER, NONPROFIT HEALTH SERVICE PLAN
16	OR HEALTH MAINTENANCE ORGANIZATION, OR AN AFFILIATE, SUBSIDIARY, OF
17	OTHER RELATED ENTITY OF AN INSURER, NONPROFIT HEALTH SERVICE PLAN
18	OR HEALTH MAINTENANCE ORGANIZATION ACTING OR REPRESENTING ITSELF
19	AS A PHARMACY BENEFITS MANAGER IF:
20	(1) THE INSURER, NONPROFIT HEALTH SERVICE PLAN, OF
21	HEALTH MAINTENANCE ORGANIZATION OR THE AFFILIATE, SUBSIDIARY, OF
22	OTHER RELATED ENTITY OF THE INSURER, NONPROFIT HEALTH SERVICE PLAN
23	OR HEALTH MAINTENANCE ORGANIZATION DIRECTLY OFFERS OR PROVIDES
24	PHARMACY BENEFITS MANAGEMENT SERVICES; AND
25	(2) THE PHARMACY BENEFITS MANAGEMENT SERVICES ARE
26	OFFERED OR PROVIDED ONLY TO ENROLLEES, SUBSCRIBERS, OR INSUREDS
27	WHO ALSO ARE COVERED BY HEALTH BENEFITS OFFERED OR PROVIDED BY THE

- 1 INSURER, NONPROFIT HEALTH SERVICE PLAN, OR HEALTH MAINTENANCE
- 2 **ORGANIZATION.**
- 3 **15–1603.**
- 4 (A) A PERSON SHALL REGISTER WITH THE COMMISSIONER BEFORE THE
- 5 PERSON ACTS AS OR REPRESENTS ITSELF AS A PHARMACY BENEFITS MANAGER
- 6 IN THE STATE.
- 7 (B) AN APPLICANT FOR REGISTRATION SHALL:
- 8 (1) FILE WITH THE COMMISSIONER AN APPLICATION ON THE
- 9 FORM THAT THE COMMISSIONER PROVIDES; AND
- 10 (2) PAY TO THE COMMISSIONER A REGISTRATION FEE SET BY THE
- 11 **COMMISSIONER.**
- 12 (C) THE COMMISSIONER SHALL REGISTER EACH APPLICANT THAT
- 13 MEETS THE REQUIREMENTS ESTABLISHED BY THE COMMISSIONER BY
- 14 **REGULATION.**
- 15 **15–1604.**
- 16 (A) A REGISTRATION EXPIRES AT THE END OF EVERY OTHER JUNE 30,
- 17 UNLESS IT IS RENEWED AS PROVIDED IN THIS SECTION.
- 18 (B) BEFORE A REGISTRATION EXPIRES, THE REGISTRANT MAY RENEW
- 19 IT FOR AN ADDITIONAL 2-YEAR TERM, IF THE REGISTRANT:
- 20 (1) OTHERWISE IS ENTITLED TO BE REGISTERED;
- 21 (2) FILES WITH THE COMMISSIONER A RENEWAL APPLICATION
- 22 ON THE FORM THAT THE COMMISSIONER REQUIRES; AND
- 23 (3) PAYS TO THE COMMISSIONER A RENEWAL FEE SET BY THE
- 24 COMMISSIONER.

- 1 (C) AN APPLICATION FOR RENEWAL OF A REGISTRATION SHALL BE
- 2 CONSIDERED TIMELY IF POSTMARKED ON OR BEFORE JUNE 30 OF THE YEAR OF
- 3 THE RENEWAL.
- 4 **15–1605.**
- 5 A PHARMACY BENEFITS MANAGER MAY NOT:
- 6 (1) VIOLATE ANY PROVISION OF THIS ARTICLE APPLICABLE TO THE PHARMACY BENEFITS MANAGER;
- 8 (2) VIOLATE ANY REGULATION ADOPTED UNDER THIS ARTICLE 9 APPLICABLE TO THE PHARMACY BENEFITS MANAGER;
- 10 (3) KNOWINGLY FAIL TO COMPLY WITH AN ORDER OF THE 11 COMMISSIONER;
- 12 **(4)** OBTAIN OR ATTEMPT TO OBTAIN A REGISTRATION BASED ON 13 INACCURATE INFORMATION;
- 14 **(5)** FRAUDULENTLY OR DECEPTIVELY OBTAIN OR USE A 15 REGISTRATION;
- 16 **(6)** FAIL TO PROTECT THE CONFIDENTIALITY OF MEDICAL RECORDS IN ACCORDANCE WITH APPLICABLE STATE AND FEDERAL LAWS; OR
- 18 (7) ACT AS A PHARMACY BENEFITS MANAGER WITHOUT FIRST 19 REGISTERING WITH THE COMMISSIONER.
- 20 **15–1606.**
- 21 (A) SUBJECT TO THE HEARING PROVISIONS OF TITLE 2 OF THIS
- 22 ARTICLE, THE COMMISSIONER MAY DENY, SUSPEND, OR REVOKE A
- 23 REGISTRATION OR REFUSE TO RENEW A REGISTRATION IF THE APPLICANT OR
- 24 REGISTRANT VIOLATES ANY PROVISION OF § 15–1605 OF THIS SUBTITLE.
- 25 (B) IF THE REGISTRATION OF A PHARMACY BENEFITS MANAGER IS
- 26 SUSPENDED OR REVOKED, THE COMMISSIONER, TO PROTECT THE INTERESTS
- 27 OF BENEFICIARIES AND PHARMACY PROVIDERS, MAY PERMIT THE CONTINUED

- 1 OPERATION OF THE PHARMACY BENEFITS MANAGER FOR A LIMITED PERIOD,
- 2 NOT TO EXCEED 60 DAYS, UNDER CONDITIONS AND RESTRICTIONS DETERMINED
- 3 BY THE COMMISSIONER.
- 4 **15–1607.**
- 5 (A) A PHARMACY BENEFITS MANAGER SHALL REGISTER WITH THE
- 6 COMMISSIONER AS A THIRD PARTY ADMINISTRATOR UNDER TITLE 8, SUBTITLE
- 7 3 OF THIS ARTICLE IF THE PHARMACY BENEFITS MANAGER:
- 8 (1) PROCESSES PRESCRIPTION DRUG CLAIMS; OR
- 9 (2) ADMINISTERS PAYMENTS RELATED TO PRESCRIPTION DRUG
- 10 CLAIMS.
- 11 (B) A PHARMACY BENEFITS MANAGER THAT PROCESSES PRESCRIPTION
- 12 DRUG CLAIMS OR ADMINISTERS PAYMENTS RELATED TO PRESCRIPTION DRUG
- 13 **CLAIMS SHALL:**
- 14 (1) PAY CLAIMS IN ACCORDANCE WITH § 15–1005 OF THIS TITLE;
- 15 **AND**
- 16 (2) ADJUST CLAIMS IN ACCORDANCE WITH § 15–1008 OF THIS
- 17 **TITLE.**
- 18 **15–1608.**
- 19 A PHARMACY BENEFITS MANAGER THAT CONDUCTS UTILIZATION REVIEW
- 20 SHALL OBTAIN FROM THE COMMISSIONER A CERTIFICATE OF REGISTRATION AS
- 21 A PRIVATE REVIEW AGENT UNDER SUBTITLE 10B OF THIS TITLE.
- 22 **15–1609.**
- 23 AN INSURER, NONPROFIT HEALTH SERVICE PLAN, OR HEALTH
- 24 MAINTENANCE ORGANIZATION MAY NOT ENTER INTO AN AGREEMENT WITH A
- 25 PHARMACY BENEFITS MANAGER THAT HAS NOT REGISTERED WITH THE
- 26 COMMISSIONER.
- 27 **15–1610.**

- 1 (A) WHENEVER THE COMMISSIONER CONSIDERS IT ADVISABLE, THE
- 2 COMMISSIONER SHALL EXAMINE THE AFFAIRS, TRANSACTIONS, ACCOUNTS,
- 3 RECORDS, AND ASSETS OF EACH PHARMACY BENEFITS MANAGER.
- 4 (B) THE EXAMINATION SHALL BE CONDUCTED IN ACCORDANCE WITH § 5 2–207 OF THIS ARTICLE.
- 6 (C) THE EXPENSE OF THE EXAMINATION SHALL BE PAID IN 7 ACCORDANCE WITH § 2–208 OF THIS ARTICLE.
- 8 (D) THE REPORTS OF THE EXAMINATION AND INVESTIGATION SHALL BE 9 ISSUED IN ACCORDANCE WITH § 2–209 OF THIS ARTICLE.
- 10 **15–1611.**
- A PHARMACY BENEFITS MANAGER SHALL MAINTAIN ADEQUATE BOOKS
- 12 AND RECORDS ABOUT EACH PURCHASER FOR WHICH THE PHARMACY BENEFITS
- 13 MANAGER PROVIDES PHARMACY BENEFITS MANAGEMENT SERVICES:
- 14 (1) IN ACCORDANCE WITH PRUDENT STANDARDS OF RECORD
- 15 **KEEPING:**
- 16 (2) FOR THE DURATION OF THE AGREEMENT BETWEEN THE
- 17 PHARMACY BENEFITS MANAGER AND THE PURCHASER; AND
- 18 (3) FOR 3 YEARS AFTER THE PHARMACY BENEFITS MANAGER
- 19 CEASES TO PROVIDE PHARMACY BENEFITS MANAGEMENT SERVICES TO THE
- 20 **PURCHASER.**
- 21 **15–1612.**
- ON OR BEFORE APRIL 1, 2008, THE COMMISSIONER SHALL ADOPT
- 23 REGULATIONS TO IMPLEMENT THIS SUBTITLE.
- 24 **15–1613.**
- 25 (A) A PHARMACY BENEFITS MANAGER SHALL DISCLOSE TO A
- 26 PROSPECTIVE PURCHASER IN WRITING:

1	(1)	THE	AMOUNT	\mathbf{OF}	ALL	REBATES,	ADMINISTRATIVE	FEES
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- 2 DETAILING PAYMENTS, EDUCATIONAL PAYMENTS, AND OTHER RETROSPECTIVE
- 3 DISCOUNTS THAT THE PHARMACY BENEFITS MANAGER ESTIMATES IT WOULD
- 4 RECEIVE, DIRECTLY OR INDIRECTLY, FROM PHARMACEUTICAL
- 5 MANUFACTURERS OR LABELERS IN CONNECTION WITH PRESCRIPTION DRUG
- 6 BENEFITS SPECIFIC TO THE PROSPECTIVE PURCHASER, IF THE PROSPECTIVE
- 7 PURCHASER WERE TO CONTRACT WITH THE PHARMACY BENEFITS MANAGER;
- 8 (2) THE NATURE, TYPE, AND AMOUNT OF ALL OTHER REVENUE
- 9 THAT THE PHARMACY BENEFITS MANAGER ESTIMATES IT WOULD RECEIVE,
- 10 DIRECTLY OR INDIRECTLY, FROM PHARMACEUTICAL MANUFACTURERS OR
- 11 LABELERS IN CONNECTION WITH PRESCRIPTION DRUG BENEFITS SPECIFIC TO
- 12 THE PROSPECTIVE PURCHASER, IF THE PROSPECTIVE PURCHASER WERE TO
- 13 CONTRACT WITH THE PHARMACY BENEFITS MANAGER;
- 14 (3) ANY ADMINISTRATIVE OR OTHER FEES THAT WOULD BE
- 15 CHARGED BY THE PHARMACY BENEFITS MANAGER TO THE PROSPECTIVE
- 16 **PURCHASER**;
- 17 (4) ANY ARRANGEMENTS WITH PRESCRIBING PROVIDERS,
- 18 MEDICAL GROUPS, INDIVIDUAL PRACTICE ASSOCIATIONS, PHARMACY
- 19 PROVIDERS, OR OTHER PERSONS THAT ARE ASSOCIATED WITH ACTIVITIES OF
- 20 THE PHARMACY BENEFITS MANAGER TO ENCOURAGE FORMULARY COMPLIANCE
- 21 OR OTHERWISE MANAGE PRESCRIPTION DRUG BENEFITS; AND
- 22 (5) A LIST OF ANY DRUGS THAT THE PHARMACY BENEFITS
- 23 MANAGER, DIRECTLY OR INDIRECTLY, REPACKAGED AND ASSIGNED NEW OR
- 24 DIFFERENT NATIONAL DRUG CODE NUMBERS INCLUDING, FOR EACH DRUG ON
- **25 THE LIST:**
- 26 (I) THE DRUG NAME AND STRENGTH;
- 27 (II) THE ORIGINAL NATIONAL DRUG CODE NUMBER AND
- 28 THE NEW NATIONAL DRUG CODE NUMBER; AND
- 29 (III) THE ORIGINAL PRICE AND THE NEW PRICE.
- 30 (B) THE DISCLOSURE REQUIRED UNDER SUBSECTION (A)(1) OF THIS
- 31 **SECTION SHALL BE PROVIDED:**

- 1 (1) IN THE AGGREGATE;
- 2 (2) FOR EACH THERAPEUTIC CLASS OF DRUGS ON A LIST OF 3 SPECIFIED THERAPEUTIC CLASSES; AND
- 4 (3) FOR FIVE INDIVIDUAL PRESCRIBED DRUGS IN EACH 5 THERAPEUTIC CLASS OF DRUGS AS REQUESTED BY THE PURCHASER.
- 6 (C) A THERAPEUTIC CLASS SHALL INCLUDE AT LEAST TWO DRUGS.
- 7 **15–1614.**
- 8 (A) AT LEAST QUARTERLY, A PHARMACY BENEFITS MANAGER SHALL
- 9 DISCLOSE TO A PURCHASER IN WRITING:
- 10 (1) THE AMOUNT OF ALL REBATES, ADMINISTRATIVE FEES,
- 11 DETAILING PAYMENTS, EDUCATIONAL PAYMENTS, AND OTHER RETROSPECTIVE
- 12 DISCOUNTS THAT THE PHARMACY BENEFITS MANAGER RECEIVES, DIRECTLY OR
- 13 INDIRECTLY, FROM PHARMACEUTICAL MANUFACTURERS OR LABELERS IN
- 14 CONNECTION WITH PRESCRIPTION DRUG BENEFITS SPECIFIC TO THE
- 15 **PURCHASER:**
- 16 (2) THE NATURE, TYPE, AND AMOUNT OF ALL OTHER REVENUE
- 17 THAT THE PHARMACY BENEFITS MANAGER RECEIVES, DIRECTLY OR
- 18 INDIRECTLY, FROM PHARMACEUTICAL MANUFACTURERS OR LABELERS IN
- 19 CONNECTION WITH PRESCRIPTION DRUG BENEFITS SPECIFIC TO THE
- 20 **PURCHASER**;
- 21 (3) ANY PRESCRIPTION DRUG UTILIZATION INFORMATION
- 22 RELATED TO UTILIZATION BY THE PURCHASER'S BENEFICIARIES OF
- 23 AGGREGATE UTILIZATION DATA THAT IS NOT SPECIFIC TO AN INDIVIDUAL
- 24 BENEFICIARY, PRESCRIBER, OR PURCHASER;
- 25 (4) ANY ADMINISTRATIVE OR OTHER FEES CHARGED BY THE
- 26 PHARMACY BENEFITS MANAGER TO THE PURCHASER;
- 27 (5) ANY ARRANGEMENTS WITH PRESCRIBING PROVIDERS,
- 28 MEDICAL GROUPS, INDIVIDUAL PRACTICE ASSOCIATIONS, PHARMACY

1	PROVIDERS, OR OTHER PERSONS THAT ARE ASSOCIATED WITH ACTIVITIES OF
2	THE PHARMACY BENEFITS MANAGER TO ENCOURAGE FORMULARY COMPLIANCE
3	OR OTHERWISE MANAGE PRESCRIPTION DRUG BENEFITS;
4	(6) A LIST OF ANY DRUGS THAT THE PHARMACY BENEFITS
5	MANAGER, DIRECTLY OR INDIRECTLY, REPACKAGED AND ASSIGNED NEW OR
6	DIFFERENT NATIONAL DRUG CODE NUMBERS INCLUDING, FOR EACH DRUG ON
7	THE LIST:
8	(I) THE DRUG NAME AND STRENGTH;
9	(II) THE ORIGINAL NATIONAL DRUG CODE NUMBER AND
10	THE NEW NATIONAL DRUG CODE NUMBER; AND
11	(III) THE ORIGINAL PRICE AND THE NEW PRICE; AND
12	(7) A LIST OF PRESCRIPTIONS FOR WHICH THERE WAS A
13	DIFFERENCE BETWEEN THE PRICE PAID TO A RETAIL PHARMACY AND THE
14	AMOUNT THAT WAS BILLED TO THE PURCHASER INCLUDING, FOR EACH
15	PRESCRIPTION:
16	(I) THE PRESCRIPTION NUMBER;
17	(II) THE DATE THE PRESCRIPTION WAS PROCESSED BY THE
18	PHARMACY BENEFITS MANAGER;
19	(III) THE NATIONAL DRUG CODE NUMBER;
20	(IV) THE BENEFICIARY'S NAME; AND
21	(V) THE PRICE PAID TO THE RETAIL PHARMACY AND THE
22	AMOUNT BILLED TO THE PURCHASER.
23	(B) THE DISCLOSURE REQUIRED UNDER SUBSECTION (A)(1) OF THIS
24	SECTION SHALL BE PROVIDED:
25	(1) IN THE AGGREGATE;
	·

- 1 (2) FOR EACH THERAPEUTIC CLASS OF DRUGS ON A LIST OF 2 SPECIFIED THERAPEUTIC CLASSES; AND
- 3 (3) FOR FIVE INDIVIDUAL PRESCRIBED DRUGS IN EACH 4 THERAPEUTIC CLASS OF DRUGS AS REQUESTED BY THE PURCHASER.
- 5 (C) A THERAPEUTIC CLASS SHALL INCLUDE AT LEAST TWO DRUGS.
- 6 **15–1615.**
- 7 (A) EXCEPT FOR UTILIZATION INFORMATION, AND EXCEPT AS
 8 PROVIDED IN SUBSECTION (D) OF THIS SECTION, A PHARMACY BENEFITS
 9 MANAGER NEED NOT MAKE THE DISCLOSURES REQUIRED UNDER §§ 15–1613
 10 AND 15–1614 OF THIS SUBTITLE UNLESS AND UNTIL THE PROSPECTIVE
 11 PURCHASER OR THE PURCHASER AGREES IN WRITING TO MAINTAIN AS
 12 CONFIDENTIAL ANY PROPRIETARY INFORMATION DISCLOSED BY THE
 13 PHARMACY BENEFITS MANAGER.
- 14 (B) THE AGREEMENT UNDER SUBSECTION (A) OF THIS SECTION MAY:
- 15 **(1)** PROVIDE FOR EQUITABLE AND LEGAL REMEDIES IN THE 16 EVENT OF A VIOLATION OF THE AGREEMENT; AND
- 17 **(2)** INCLUDE PERSONS WITH WHICH THE PROSPECTIVE
 18 PURCHASER OR PURCHASER CONTRACTS TO PROVIDE CONSULTING SERVICES
 19 RELATING TO PHARMACY BENEFITS MANAGEMENT SERVICES.
 - (C) PROPRIETARY INFORMATION INCLUDES:
- 21 (1) TRADE SECRETS; AND
- 22 (2) INFORMATION ABOUT PRICING, COSTS, REVENUES, TAXES,
- 23 MARKET SHARE, NEGOTIATING STRATEGIES, CUSTOMERS, AND PERSONNEL
- 24 HELD BY A PHARMACY BENEFITS MANAGER AND USED FOR ITS BUSINESS
- 25 **PURPOSES.**

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

1	15–	16	16.

- A CONTRACT EXECUTED BY A PHARMACY BENEFITS MANAGER FOR THE PROVISION OF PHARMACY BENEFITS MANAGEMENT SERVICES SHALL INCLUDE:
- 4 (1) THE AMOUNT OF THE TOTAL REVENUES, REBATES, AND
- 5 DISCOUNTS IDENTIFIED IN §§ 15–1613 AND 15–1614 OF THIS SUBTITLE THAT
- 6 WILL BE PASSED ON TO THE PURCHASER:
- 7 (2) THE MAXIMUM ALLOWABLE COST AND AVERAGE WHOLESALE
- 8 PRICE RESOURCES USED TO DETERMINE THE PRICE PAID TO A PHARMACY AND
- 9 **BILLED TO THE PURCHASER**;
- 10 (3) THE CONDITIONS UNDER WHICH BENEFICIARY UTILIZATION
- 11 DATA MAY BE DISCLOSED OR SOLD BY THE PHARMACY BENEFITS MANAGER TO
- 12 ANY PERSON OTHER THAN THE PURCHASER;
- 13 (4) ANY ADMINISTRATIVE OR OTHER FEES:
- 14 (I) CHARGED BY THE PHARMACY BENEFITS MANAGER TO
- 15 THE PURCHASER; OR
- 16 (II) COLLECTED BY THE PHARMACY BENEFITS MANAGER ON
- 17 BEHALF OF THE PURCHASER;
- 18 (5) (I) THE CONDITIONS UNDER WHICH AN AUDIT WILL BE
- 19 CONDUCTED OF THE CONTRACT FOR PHARMACY BENEFITS MANAGEMENT
- 20 **SERVICES**;
- 21 (II) WHO WILL CONDUCT THE AUDIT; AND
- 22 (III) WHO WILL PAY FOR THE AUDIT;
- 23 (6) ANY REVENUES, REBATES, OR DISCOUNTS RECEIVED,
- 24 DIRECTLY OR INDIRECTLY, BY THE PHARMACY BENEFITS MANAGER FROM
- 25 PERSONS OTHER THAN PHARMACEUTICAL MANUFACTURERS AND LABELERS
- 26 THAT ARE SPECIFIC TO THE PHARMACY BENEFITS MANAGEMENT SERVICES TO
- 27 BE PROVIDED TO THE PURCHASER;

1	(7) THE PROCESS FOR THE DEVELOPMENT OF FORMULARIES,
2	NOTIFICATION OF CHANGES TO FORMULARIES, AND APPROVAL OF CHANGES BY
3	THE PURCHASER; AND
3	THE I CHCHASER, AND
4	(8) AN AGREEMENT TO PROVIDE TO THE PURCHASER A LIST OF
5	PRESCRIPTIONS FOR WHICH THERE WAS A DIFFERENCE BETWEEN THE PRICE
6	PAID TO A RETAIL PHARMACY AND THE AMOUNT THAT WILL BE OR WAS BILLED
7	TO THE PURCHASER INCLUDING, FOR EACH PRESCRIPTION:
8	(I) THE PRESCRIPTION NUMBER;
9	(II) THE DATE THE DESCRIPTION DRIC WAS DECCESSED
	(II) THE DATE THE PRESCRIPTION DRUG WAS PROCESSED
10	BY THE PHARMACY BENEFITS MANAGER;
11	(III) WHE NATIONAL DRIVE CODE NUMBER.
11	(III) THE NATIONAL DRUG CODE NUMBER;
10	(IV) WHE DENIED OLD DY'C NAME, AND
12	(IV) THE BENEFICIARY'S NAME; AND
13	(V) THE PRICE PAID TO THE RETAIL PHARMACY AND THE
13	AMOUNT BILLED TO THE PURCHASER.
14	AMOUNT BILLED TO THE PURCHASER.
15	15–1617.
13	10-1017.
16	(A) (1) EACH MEMBER OF A PHARMACY AND THERAPEUTICS
17	COMMITTEE FOR A PHARMACY BENEFITS MANAGER SHALL BE:
1 /	COMMITTEE FOR AT HARMACT BENEFITS MANAGER SHALL BE.
18	(I) A PHYSICIAN OR OTHER AUTHORIZED PRESCRIBER, A
19	PHARMACIST, OR A FACULTY MEMBER OF AN ACADEMIC MEDICAL CENTER; AND
19	FILARMACIST, OR A FACULTT MEMBER OF AN ACADEMIC MEDICAL CENTER, AND
20	(II) DISCLOSED BY NAME TO THE PURCHASER ON REQUEST.
20	(II) DISCLOSED BY NAME TO THE FUNCHASER ON REQUEST.
21	(2) A MAJORITY OF COMMITTEE MEMBERS MAY NOT BE
22	EMPLOYED BY THE PHARMACY BENEFITS MANAGER.
22	EMPLOTED BY THE PHARMACT DENEFTIS MANAGER.
22	(B) A PHARMACY AND THERAPEUTICS COMMITTEE MEMBER MAY NOT:
23	(B) A PHARMACY AND THERAPEUTICS COMMITTEE MEMBER MAY NOT:
24	(1) DE AN OFFICED EMDLOVEE DIDECTOR OF ACTIVE OF A
24 25	(1) BE AN OFFICER, EMPLOYEE, DIRECTOR, OR AGENT OF A
43	PHARMACEUTICAL MANUFACTURER; OR

1	(2)	HAVE	Α	FINANCIAL	INTEREST	IN	Α	PHARMACEUTICAL
1	(4)		$\boldsymbol{\Lambda}$	LIMATORE		TT.		1 IIMIMIACE CITCAL

- 2 MANUFACTURER, OTHER THAN OWNERSHIP OF A NOMINAL NUMBER OF SHARES
- 3 OF THE PHARMACEUTICAL MANUFACTURER'S STOCK, PURCHASED ON A
- 4 NATIONAL SECURITIES EXCHANGE.
- 5 **15–1618.**
- 6 (A) A PHARMACY BENEFITS MANAGER MAY NOT SUBSTITUTE ANOTHER
- 7 PRESCRIPTION DRUG FOR THE CURRENTLY PRESCRIBED PRESCRIPTION DRUG
- 8 UNLESS:
- 9 (1) THE SUBSTITUTION IS MADE FOR MEDICAL REASONS THAT
- 10 BENEFIT THE BENEFICIARY; OR
- 11 (2) THE SUBSTITUTION RESULTS IN FINANCIAL SAVINGS AND
- 12 BENEFITS TO THE PURCHASER.
- 13 (B) IF A PRESCRIPTION DRUG SUBSTITUTION IS MADE UNDER THIS
- 14 SECTION, THE PHARMACY BENEFITS MANAGER SHALL DISCLOSE TO THE
- 15 PURCHASER ANY BENEFIT OR PAYMENT RECEIVED IN ANY FORM BY THE
- 16 PHARMACY BENEFITS MANAGER FROM A PHARMACEUTICAL MANUFACTURER
- 17 OR OTHER PERSON RELATED TO THE SUBSTITUTION.
- 18 (C) EXCEPT AS PROVIDED IN SUBSECTION (E) OF THIS SECTION, A
- 19 PHARMACY BENEFITS MANAGER SHALL:
- 20 (1) OBTAIN AUTHORIZATION FROM A PRESCRIBER TO
- 21 SUBSTITUTE ANOTHER PRESCRIPTION DRUG FOR A CURRENTLY PRESCRIBED
- 22 PRESCRIPTION DRUG; AND
- 23 (2) DISCLOSE TO THE PRESCRIBER:
- 24 (I) THE COST SAVINGS FOR THE PURCHASER, IF ANY, THAT
- 25 RESULT FROM THE DRUG SUBSTITUTION;
- 26 (II) THE DIFFERENCE, IF ANY, IN COPAYMENTS OR OTHER
- 27 OUT-OF-POCKET COSTS PAID BY THE BENEFICIARY TO OBTAIN THE
- 28 **SUBSTITUTE DRUG**;

- 1 (III) THE EXISTENCE OF ADDITIONAL PAYMENTS RECEIVED
- 2 BY THE PHARMACY BENEFITS MANAGER THAT ARE NOT REFLECTED IN THE
- 3 COST SAVINGS TO THE PURCHASER;
- 4 (IV) THE CIRCUMSTANCES, IF ANY, UNDER WHICH THE
- 5 CURRENTLY PRESCRIBED DRUG WILL BE COVERED;
- 6 (V) THE CIRCUMSTANCES, IF ANY, AND EXTENT TO WHICH
- 7 HEALTH CARE COSTS RELATED TO THE DRUG SUBSTITUTION WILL BE
- 8 **COMPENSATED**; AND
- 9 (VI) ANY KNOWN DIFFERENCES IN POTENTIAL EFFECTS ON A
- 10 BENEFICIARY'S HEALTH AND SAFETY, INCLUDING SIDE EFFECTS.
- 11 (D) IF AUTHORIZATION IS GIVEN VERBALLY, A PHARMACY BENEFITS
- 12 MANAGER SHALL RECORD THE NAME AND TITLE OF THE PRESCRIBER
- 13 AUTHORIZING THE PRESCRIPTION DRUG SUBSTITUTION.
- 14 (E) A PHARMACY BENEFITS MANAGER MAY MAKE A PRESCRIPTION
- 15 DRUG SUBSTITUTION WITHOUT OBTAINING AUTHORIZATION FROM A
- 16 PRESCRIBER OR MAKING THE DISCLOSURES REQUIRED UNDER SUBSECTION (C)
- 17 **OF THIS SECTION IF:**
- 18 (1) THE SUBSTITUTION IS FROM A BRAND NAME DRUG TO A
- 19 GENERIC DRUG, AND THE SUBSTITUTION IS MADE IN ACCORDANCE WITH
- 20 § 12–504 OF THE HEALTH OCCUPATIONS ARTICLE;
- 21 (2) THE CURRENTLY PRESCRIBED DRUG IS NO LONGER
- 22 AVAILABLE IN THE MARKET; OR
- 23 (3) THE SUBSTITUTION IS REQUIRED FOR COVERAGE REASONS
- 24 BECAUSE THE PRESCRIBED DRUG IS NOT COVERED BY THE BENEFICIARY'S
- 25 FORMULARY OR PLAN.
- 26 (F) A PHARMACY BENEFITS MANAGER MAY NOT SUBSTITUTE ANOTHER
- 27 PRESCRIPTION DRUG FOR A CURRENTLY PRESCRIBED PRESCRIPTION DRUG
- 28 UNLESS THE PHARMACY BENEFITS MANAGER PROVIDES THE BENEFICIARY OR
- 29 THE BENEFICIARY'S REPRESENTATIVE THE FOLLOWING:

1	(1)	UNLESS	THE	SUBSTITUTION	WAS	EXEMPTED	UNDER
2	SUBSECTION (E)	OF THIS SI	ECTION	, A NOTIFICATION	THAT:		

- 3 (I) THE PHARMACY BENEFITS MANAGER REQUESTED A
 4 DRUG SUBSTITUTION BY CONTACTING THE BENEFICIARY'S PRESCRIBER; AND
- 5 (II) THE PRESCRIBER APPROVED THE DRUG SUBSTITUTION;
- 6 (2) THE NAMES OF THE PROPOSED DRUG SUBSTITUTION AND THE 7 CURRENTLY PRESCRIBED DRUG;
- 8 (3) THE DIFFERENCE, IF ANY, IN COPAYMENTS OR OTHER 9 OUT-OF-POCKET COSTS PAID BY THE BENEFICIARY TO OBTAIN THE 10 SUBSTITUTE DRUG;
- 11 (4) ANY KNOWN DIFFERENCES IN POTENTIAL EFFECTS ON A
 12 BENEFICIARY'S HEALTH AND SAFETY, INCLUDING SIDE EFFECTS;
- 13 **(5)** THE CIRCUMSTANCES, IF ANY, UNDER WHICH THE 14 CURRENTLY PRESCRIBED DRUG WILL BE COVERED;
- 15 **(6)** THE CIRCUMSTANCES, IF ANY, AND THE EXTENT TO WHICH 16 HEALTH CARE COSTS RELATED TO THE DRUG SUBSTITUTION WILL BE 17 COMPENSATED;
- 18 (7) A NOTIFICATION THAT THE BENEFICIARY MAY DECLINE THE
 19 DRUG SUBSTITUTION IF THE CURRENTLY PRESCRIBED DRUG REMAINS ON THE
 20 BENEFICIARY'S FORMULARY, AND THE BENEFICIARY IS WILLING TO PAY ANY
 21 DIFFERENCE IN THE COPAYMENT AMOUNT; AND
- 22 **(8)** A TOLL-FREE TELEPHONE NUMBER TO COMMUNICATE WITH 23 THE PHARMACY BENEFITS MANAGER.
- 24 (G) (1) A PHARMACY BENEFITS MANAGER SHALL CANCEL AND
 25 REVERSE A PRESCRIPTION DRUG SUBSTITUTION ON WRITTEN OR VERBAL
 26 INSTRUCTIONS FROM A PRESCRIBER, THE BENEFICIARY, OR THE
 27 BENEFICIARY'S REPRESENTATIVE.

- 1 (2) If A PRESCRIBER, THE BENEFICIARY, OR THE BENEFICIARY'S
 2 REPRESENTATIVE CANCELS AND REVERSES A DRUG SUBSTITUTION, THE
 3 PHARMACY BENEFITS MANAGER SHALL:
- 4 (I) OBTAIN A PRESCRIPTION FOR AND DISPENSE THE 5 CURRENTLY PRESCRIBED DRUG;
- 6 (II) CHARGE THE BENEFICIARY ONLY ONE COPAYMENT; AND
- 7 (III) IF A BENEFICIARY WILL EXHAUST THE SUPPLY OF THE 8 CURRENTLY PRESCRIBED DRUG BEFORE A REPLACEMENT SHIPMENT WILL
- 9 ARRIVE TO THE BENEFICIARY, ARRANGE FOR DISPENSING OF AN APPROPRIATE
- 10 QUANTITY OF REPLACEMENT DRUGS AT A RETAIL OR INSTITUTIONAL
- 11 PHARMACY AT NO ADDITIONAL COST TO THE BENEFICIARY.
- 12 (3) A PHARMACY BENEFITS MANAGER MAY NOT BE REQUIRED TO CANCEL AND REVERSE A DRUG SUBSTITUTION IF:
- 14 (I) THE PRESCRIBED DRUG IS NO LONGER ON THE 15 PURCHASER'S FORMULARY; OR
- 16 (II) A BENEFICIARY IS UNWILLING TO PAY A HIGHER
 17 COPAYMENT OR OTHER COST ASSOCIATED WITH THE PRESCRIBED DRUG.
- 18 (H) A PHARMACY BENEFITS MANAGER SHALL MAINTAIN A TOLL-FREE 19 TELEPHONE NUMBER 24 HOURS A DAY, 7 DAYS A WEEK, FOR PRESCRIBERS, 20 PHARMACY PROVIDERS, AND BENEFICIARIES.
- 21 **15–1619.**
- 22 (A) IF THE PHARMACY BENEFITS MANAGEMENT SERVICES PERFORMED
- 23 BY A PHARMACY BENEFITS MANAGER FOR A PURCHASER INCLUDE
- 24 NEGOTIATING OR ENTERING INTO CONTRACTUAL ARRANGEMENTS WITH
- 25 PHARMACY PROVIDERS, BEFORE THE PHARMACY BENEFITS MANAGER MAY
- 26 PROVIDE PHARMACY BENEFITS MANAGEMENT SERVICES FOR THE PURCHASER,
- 27 THE PHARMACY BENEFITS MANAGER SHALL ENTER INTO ANY NECESSARY
- 28 WRITTEN CONTRACTS WITH PHARMACY PROVIDERS.

- 1 (B) A CONTRACT WITH A PHARMACY PROVIDER SHALL REQUIRE THE 2 PHARMACY BENEFITS MANAGER TO:
- 3 (1) DISCLOSE TO THE PHARMACY PROVIDER:
- 4 (I) THE TERMS, CONDITIONS, FEES, BENEFIT DESIGNS,
- 5 PROCESS, AND PROCEDURES FOR ACCESSING THE PHARMACY BENEFITS
- 6 MANAGEMENT SERVICES PROVIDED BY THE PHARMACY BENEFITS MANAGER;
- 7 **AND**
- 8 (II) THE PHARMACY BENEFITS MANAGER'S PROCEDURES
- 9 FOR HANDLING DISPUTES; AND
- 10 (2) PROVIDE AT LEAST 30 DAYS' WRITTEN NOTICE TO THE
- 11 PHARMACY PROVIDER OF BENEFIT CHANGES, INCLUDING ADDITIONS OR
- 12 DELETIONS TO COVERED PRESCRIPTION DRUGS, WITH THE EXCEPTION OF NEW
- 13 DRUGS APPROVED BY THE U.S. FOOD AND DRUG ADMINISTRATION.
- 14 **15–1620.**
- 15 THE FOLLOWING PROVISIONS SHALL APPLY TO ANY AUDITS CARRIED OUT
- 16 BY PHARMACY BENEFITS MANAGERS OF PHARMACIES OR CLAIMS FROM
- 17 **PHARMACIES:**
- 18 (1) ONLY CLAIMS THAT HAVE BEEN REQUESTED FOR AUDITING
- 19 MAY BE SUBJECT TO AN AUDIT;
- 20 (2) A PHARMACY BENEFITS MANAGER MAY NOT REQUIRE
- 21 EXTRAPOLATION AUDITS AS A CONDITION OF A CONTRACT OR PARTICIPATION
- 22 IN A NETWORK OR PROGRAM OF THE PHARMACY BENEFITS MANAGER;
- 23 (3) A PHARMACY BENEFITS MANAGER MAY NOT RECOUP BY
- 24 SETOFF ANY MONEYS THAT THE PHARMACY BENEFITS MANAGER CONTENDS
- 25 ARE DUE AS A RESULT OF AN AUDIT UNTIL THE PHARMACY HAS THE
- 26 OPPORTUNITY TO REVIEW AND CONCUR WITH THE AUDIT FINDINGS; AND
- 27 (4) IF THE PHARMACY BENEFITS MANAGER AND THE PHARMACY
- 28 CANNOT AGREE ON THE MONEYS DUE AS A RESULT OF AN AUDIT, THE

- 1 COMMISSIONER SHALL REVIEW THE AUDIT AND DETERMINE IF ANY MONEYS
- 2 ARE DUE.
- 3 **15–1621.**
- 4 A PHARMACY BENEFITS MANAGER:
- 5 (1) SHALL ALLOW A BENEFICIARY TO OBTAIN COVERED
- 6 PHARMACY SERVICES FROM THE PHARMACY PROVIDER OF THE BENEFICIARY'S
- 7 CHOICE WITHIN THE PHARMACY BENEFITS MANAGER'S NETWORK;
- 8 (2) SHALL ALLOW A RETAIL OR INSTITUTIONAL PHARMACY THAT
- 9 CAN MEET THE SAME TERMS AND CONDITIONS AS A MAIL ORDER PHARMACY TO
- 10 PROVIDE THE SAME SERVICES PROVIDED BY A MAIL ORDER PHARMACY; AND
- 11 **(3) MAY NOT:**
- 12 (I) REQUIRE A BENEFICIARY TO OBTAIN PHARMACY
- 13 SERVICES FROM A MAIL ORDER PHARMACY IF A RETAIL OR INSTITUTIONAL
- 14 PHARMACY CAN MEET THE SAME TERMS AND CONDITIONS AS THE MAIL ORDER
- 15 **PHARMACY**;
- 16 (II) USE ANY FINANCIAL OR OTHER DISINCENTIVES,
- 17 PENALTIES, OR OTHER MEANS TO INFLUENCE, COERCE, OR STEER
- 18 BENEFICIARIES AWAY FROM A RETAIL OR INSTITUTIONAL PHARMACY THAT CAN
- 19 MEET THE SAME TERMS AND CONDITIONS AS A MAIL ORDER PHARMACY; OR
- 20 (III) LIMIT THE QUANTITY OF DRUGS THAT A BENEFICIARY
- 21 MAY OBTAIN AT ANY ONE TIME FROM ANY TYPE OF PHARMACY PROVIDER,
- 22 UNLESS THE LIMIT IS APPLIED UNIFORMLY TO ALL PHARMACY PROVIDERS
- 23 THAT ARE WITHIN THE PHARMACY BENEFITS MANAGER'S NETWORK, UNDER
- 24 CONTRACT, OR OTHERWISE AUTHORIZED TO PROVIDE PHARMACY SERVICES TO
- 25 **BENEFICIARIES.**
- 26 **15–1622.**
- 27 ALL DISCLOSURES MADE UNDER THIS SUBTITLE SHALL COMPLY WITH THE
- 28 PRIVACY STANDARDS OF THE FEDERAL HEALTH INSURANCE PORTABILITY AND
- 29 **ACCOUNTABILITY ACT.**

1 **15–1623.**

IN ADDITION TO THE PENALTIES AUTHORIZED BY § 15–1606 OF THIS
SUBTITLE, THE COMMISSIONER MAY ASSESS A CIVIL PENALTY NOT EXCEEDING
4 \$10,000 AGAINST ANY PERSON THAT VIOLATES THIS SUBTITLE.

Article - Health - General

6 19–706.

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7 (JJJ) THE PROVISIONS OF § 15–805 AND TITLE 15, SUBTITLE 16 OF THE 8 INSURANCE ARTICLE APPLY TO HEALTH MAINTENANCE ORGANIZATIONS.

Article - Health Occupations

- 10 12–101.
- 11 (m) (1) "Nonresident pharmacy" means a pharmacy located outside this 12 State that, in the normal course of business, as determined by the Board, ships, mails, 13 or delivers drugs or devices to a person in this State pursuant to a prescription.
- 14 (2) "Nonresident pharmacy" includes a pharmacy 15 Benefits manager, located within or outside this State, that is 16 REGULATED UNDER TITLE 15, SUBTITLE 16 OF THE INSURANCE ARTICLE, IF 17 THE PHARMACY BENEFITS MANAGER SHIPS, MAILS, OR DELIVERS DRUGS OR 18 DEVICES TO A PERSON IN THIS STATE PURSUANT TO A PRESCRIPTION.
- 19 12–403.
- 20 (a) This section does not require a nonresident pharmacy to violate the laws 21 or regulations of the state in which it is located.
- 22 (b) Except as otherwise provided in this section, a pharmacy for which a 23 pharmacy permit has been issued under this title:
- 24 (17) With regard to a prescription drug that is delivered in this State by 25 the United States mail, a common carrier, or a delivery service and is not personally 26 hand delivered directly to a patient or to the agent of the patient at the residence of 27 the patient or at another location designated by the patient, shall:

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1 2 3 4	(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
5 6 7 8	(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;
9 10	(d) A nonresident pharmacy shall hold a pharmacy permit issued by the Board.
11 12	(e) (1) In order to obtain a pharmacy permit from the Board, a nonresident pharmacy, ${\bf TO}$ THE EXTENT APPLICABLE, shall:
13 14	(i) Submit an application to the Board on the form that the Board requires;
15	(ii) Pay to the Board an application fee set by the Board;
16 17 18	(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
19 20 21	(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.
22 23	(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.
24	(f) A nonresident pharmacy, TO THE EXTENT APPLICABLE, shall:
25	(1) Comply with the laws of the state in which it is located;
26 27 28 29	(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;

- 1 (3)Comply with all lawful directions and requests for information 2 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; 3
- 4 Maintain at all times a valid, unexpired permit to conduct a 5 pharmacy in compliance with the laws of the state in which it is located;
- 6 Maintain its records of prescription drugs or devices dispensed to 7 patients in this State so that the records are readily retrievable;
- 8 During its regular hours of operation, but not less than 6 days a (6)week, and for a minimum of 40 hours per week, provide toll-free telephone service to 9 10 facilitate communication between patients in this State and a pharmacist who has 11 access to the patient's prescription records;
- 12 Disclose its toll-free telephone number on a label affixed to each (7)13 container of drugs or devices;
- 14 Comply with the laws of this State relating to the confidentiality of 15 prescription records if there are no laws relating to the confidentiality of prescription 16 records in the state in which the nonresident pharmacy is located; [and]
- 17 (9)Comply with the requirements of subsection (b)(17) of this section; 18 **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.
 - 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.
 - 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 Marvland Insurance Commissioner, as required under Section 1 of this Act, if the person:
- 31 (1) registers with the Commissioner on or before September 1, 2008;
- 32 and

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- 1 (2) complies with all other applicable provisions of this Act.
- 2 SECTION 3. AND BE IT FURTHER ENACTED, That this Act shall take effect 3 October 1, 2007.