CHAPTER 202

(House Bill 419)

AN ACT concerning

Pharmacy Benefits Managers - Registration

FOR the purpose of requiring a person pharmacy benefits manager to register with the Maryland Insurance Commissioner before the person acts as or represents itself as a pharmacy benefits manager providing pharmacy benefits management services in the State; 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 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 pharmacy benefits managers; 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 under certain circumstances; requiring a pharmacy benefits manager to register as a third party administrator or a 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, a nonprofit health service plan, or a health maintenance organization a purchaser from entering into an agreement with a pharmacy benefits manager that has not registered with the Commissioner; requiring authorizing 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; authorizing the Commissioner to issue a certain order; authorizing an order of the Commissioner to be served in a certain manner under certain circumstances; providing that a request for a hearing on a certain order does not stay a certain portion of the order; authorizing the Commissioner to file a certain petition in circuit court; authorizing the Commissioner to recover certain fees and costs under certain circumstances; 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 certain circumstances; defining certain terms; and generally relating to regulation and registration of pharmacy benefits managers.

BY adding to

Article – Insurance

Section 15–1601 through 15–1613 <u>15–1609</u> to be under the new subtitle "Subtitle 16. Pharmacy Benefits Managers"

Annotated Code of Maryland

(2006 Replacement Volume and 2007 Supplement)

BY adding to

Article - Health - General

Section 19–706(ppp)

Annotated Code of Maryland

(2005 Replacement Volume and 2007 Supplement)

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 2007 Supplement)

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 2007 Supplement)

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

Article - Insurance

SUBTITLE 16. PHARMACY BENEFITS MANAGERS.

15–1601.

- (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.
- (B) (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:
 - (H) PROCESSING OF PRESCRIPTION DRUG CLAIMS:
- (HI) ADMINISTRATION OF PAYMENTS RELATED TO PRESCRIPTION DRUG CLAIMS; AND
- (IV) NEGOTIATING OR ENTERING INTO CONTRACTUAL ARRANGEMENTS WITH PHARMACIES OR PHARMACISTS.
- (D) "NONPROFIT HEALTH MAINTENANCE ORGANIZATION" HAS THE MEANING STATED IN § 6–121(A) OF THIS ARTICLE.
 - (E) (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. <u>CLINICAL FORMULARY DEVELOPMENT AND MANAGEMENT SERVICES;</u>
 - 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.
- (C) (F) "PHARMACY BENEFITS MANAGER" MEANS A PERSON THAT PERFORMS PHARMACY BENEFITS MANAGEMENT SERVICES.
- (D) (1) "UTILIZATION REVIEW" HAS THE MEANING STATED IN § 15–10B–01 OF THIS TITLE.
 - (2) "UTILIZATION REVIEW" INCLUDES:
 - (I) DRUG UTILIZATION MANAGEMENT;
 - (H) DRUG UTILIZATION REVIEW SERVICES; AND
 - (III) STEP PROTOCOL THERAPY MANAGEMENT.
- (G) (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 ARRANGEMENT AS DEFINED IN § 514(B)(6)(A)(II) OF ERISA.

15-1602.

- (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 THIS SUBTITLE DO NOT APPLY TO AN INSURER, A NONPROFIT HEALTH SERVICE PLAN, OR A HEALTH MAINTENANCE ORGANIZATION OR AN AFFILIATE, SUBSIDIARY, OR OTHER RELATED ENTITY OF AN INSURER, A NONPROFIT HEALTH SERVICE PLAN, OR A 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 INSUREDS WHO ALSO ARE COVERED BY HEALTH BENEFITS OFFERED OR PROVIDED BY THE INSURER, NONPROFIT HEALTH SERVICE PLAN, OR HEALTH MAINTENANCE ORGANIZATION.

15_1603

- (A) A PERSON PHARMACY BENEFITS MANAGER SHALL REGISTER WITH THE COMMISSIONER BEFORE THE PERSON ACTS AS OR REPRESENTS ITSELF AS A PHARMACY BENEFITS MANAGER IN THE STATE BEFORE PROVIDING PHARMACY BENEFITS MANAGEMENT SERVICES IN THE STATE TO PURCHASERS.
 - (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 SUBJECT TO THE PROVISIONS OF § 15–1604 OF THIS SUBTITLE, THE COMMISSIONER SHALL REGISTER EACH PHARMACY BENEFITS MANAGER THAT MEETS THE REQUIREMENTS OF THIS SECTION.

15-1604.

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

15–1603.

- (A) A PHARMACY BENEFITS MANAGER REGISTRATION EXPIRES ON THE ANNIVERSARY DATE THAT OCCURS ON THE DATE 2 YEARS FOLLOWING THE DATE THE COMMISSIONER ISSUED THE REGISTRATION, UNLESS IT IS RENEWED AS PROVIDED UNDER THIS SECTION.
- (B) BEFORE A REGISTRATION EXPIRES, THE REGISTRANT MAY RENEW IT FOR AN ADDITIONAL 2-YEAR TERM, IF THE REGISTRANT A PHARMACY BENEFITS MANAGER MAY RENEW ITS REGISTRATION FOR AN ADDITIONAL 2-YEAR TERM, IF THE PHARMACY BENEFITS MANAGER:
 - (1) OTHERWISE IS ENTITLED TO BE REGISTERED;
- (2) FILES WITH THE COMMISSIONER A RENEWAL APPLICATION ON THE FORM THAT THE COMMISSIONER REQUIRES; AND
- (3) PAYS TO THE COMMISSIONER A RENEWAL FEE SET BY THE COMMISSIONER.
- (C) AN APPLICATION FOR RENEWAL OF A <u>PHARMACY BENEFITS</u> MANAGER REGISTRATION SHALL BE CONSIDERED TIMELY IF MADE IN A TIMELY <u>MANNER IF IT IS</u> POSTMARKED ON OR BEFORE JUNE 30 OF THE YEAR OF THE RENEWAL THE DATE THE PHARMACY BENEFITS MANAGER'S REGISTRATION EXPIRES.
- (D) SUBJECT TO THE PROVISIONS OF § 15–1604 OF THIS SUBTITLE, THE COMMISSIONER SHALL RENEW THE REGISTRATION OF EACH PHARMACY BENEFITS MANAGER THAT MEETS THE REQUIREMENTS OF THIS SECTION.

15–1604.

- (A) SUBJECT TO THE HEARING PROVISIONS OF TITLE 2 OF THIS ARTICLE, THE COMMISSIONER MAY DENY A REGISTRATION TO A PHARMACY BENEFITS MANAGER APPLICANT OR REFUSE TO RENEW, SUSPEND, OR REVOKE THE REGISTRATION OF A PHARMACY BENEFITS MANAGER IF THE PHARMACY BENEFITS MANAGER, OR AN OFFICER, DIRECTOR, OR EMPLOYEE OF THE PHARMACY BENEFITS MANAGER:
- (1) MAKES A MATERIAL MISSTATEMENT OR MISREPRESENTATION IN AN APPLICATION FOR REGISTRATION;
- (2) FRAUDULENTLY OR DECEPTIVELY OBTAINS OR ATTEMPTS TO OBTAIN A REGISTRATION;
- (3) IN CONNECTION WITH THE ADMINISTRATION OF PHARMACY BENEFITS MANAGEMENT SERVICES, COMMITS FRAUD OR ENGAGES IN ILLEGAL OR DISHONEST ACTIVITIES; OR
- (4) VIOLATES ANY PROVISION OF THIS SUBTITLE OR A REGULATION ADOPTED UNDER THIS SUBTITLE.
- (B) THIS SECTION DOES NOT LIMIT ANY OTHER REGULATORY AUTHORITY OF THE COMMISSIONER UNDER THIS ARTICLE.

15–1605.

A PHARMACY BENEFITS MANAGER MAY NOT SHIP, MAIL, OR DELIVER PRESCRIPTION DRUGS OR DEVICES TO A PERSON IN THE STATE THROUGH A NONRESIDENT PHARMACY UNLESS THE NONRESIDENT PHARMACY HOLDS A PERMIT ISSUED IN ACCORDANCE WITH THE PROVISIONS OF § 12–403 OF THE HEALTH OCCUPATIONS ARTICLE.

15-1605.

A PHARMACY BENEFITS MANAGER MAY NOT:

- (1) VIOLATE ANY PROVISION OF THIS ARTICLE APPLICABLE TO THE PHARMACY BENEFITS MANAGER:
- (2) VIOLATE ANY REGULATION ADOPTED UNDER THIS ARTICLE APPLICABLE TO THE PHARMACY BENEFITS MANAGER:
- (3) KNOWINGLY FAIL TO COMPLY WITH ANY ORDER OF THE COMMISSIONER:

15-1606.

- (4) OBTAIN OR ATTEMPT TO OBTAIN A REGISTRATION BASED ON INACCURATE INFORMATION:
- (5) FRAUDULENTLY OR DECEPTIVELY OBTAIN OR USE A RECISTRATION:
- (6) FAIL TO PROTECT THE CONFIDENTIALITY OF MEDICAL RECORDS IN ACCORDANCE WITH APPLICABLE STATE AND FEDERAL LAWS; OR
- (7) ACT AS A PHARMACY BENEFITS MANAGER WITHOUT FIRST REGISTERING WITH THE COMMISSIONER.
- (A) SUBJECT TO THE HEARING PROVISIONS OF TITLE 2 OF THIS ARTICLE, THE COMMISSIONER MAY DENY, SUSPEND, OR REVOKE A REGISTRATION OR REFUSE TO RENEW A REGISTRATION IF THE APPLICANT OR RECISTRANT VIOLATES ANY PROVISION OF § 15–1605 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 PHARMACIES AND PHARMACISTS, 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.
- (A) WHENEVER THE COMMISSIONER CONSIDERS IT ADVISABLE, THE COMMISSIONER MAY EXAMINE THE AFFAIRS, TRANSACTIONS, ACCOUNTS, AND RECORDS OF A REGISTERED 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.

15–1607.

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

15-1608.

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.

15-1609.

AN INSURER, A NONPROFIT HEALTH SERVICE PLAN, OR A HEALTH MAINTENANCE ORGANIZATION MAY NOT ENTER INTO AN AGREEMENT WITH A PHARMACY BENEFITS MANAGER THAT HAS NOT REGISTERED WITH THE COMMISSIONER.

15-1610.

- (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.

15-1611.

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.

15-1612.

ON OR BEFORE APRIL 1, 2009, THE COMMISSIONER SHALL ADOPT REGULATIONS TO IMPLEMENT THIS SUBTITLE.

15-1613.

In addition to the penalties authorized by § 15-1606 of this subtitle, the Commissioner may assess a civil penalty not exceeding \$10.000 for each violation of this subtitle.

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 FOR THE PURCHASER.

15–1608.

- (A) IF THE COMMISSIONER DETERMINES THAT A PHARMACY BENEFITS MANAGER HAS VIOLATED ANY PROVISION OF THIS SUBTITLE OR ANY REGULATION ADOPTED UNDER THIS SUBTITLE, THE COMMISSIONER MAY ISSUE AN ORDER THAT REQUIRES THE PHARMACY BENEFITS MANAGER TO:
- (1) CEASE AND DESIST FROM THE IDENTIFIED VIOLATION AND FURTHER SIMILAR VIOLATIONS;
- (2) TAKE SPECIFIC AFFIRMATIVE ACTION TO CORRECT THE VIOLATION; OR
- (3) MAKE RESTITUTION OF MONEY, PROPERTY, OR OTHER ASSETS TO A PERSON THAT HAS SUFFERED FINANCIAL INJURY BECAUSE OF THE VIOLATION.
- (B) (1) AN ORDER OF THE COMMISSIONER ISSUED UNDER THIS SECTION MAY BE SERVED ON A PHARMACY BENEFITS MANAGER THAT IS REGISTERED UNDER THIS SUBTITLE IN THE MANNER PROVIDED IN § 2–204 OF THIS ARTICLE.
- (2) AN ORDER OF THE COMMISSIONER ISSUED UNDER THIS SECTION MAY BE SERVED ON A PHARMACY BENEFITS MANAGER THAT IS NOT REGISTERED UNDER THIS SUBTITLE IN THE MANNER PROVIDED IN § 4–206 OR § 4–207 OF THIS ARTICLE FOR SERVICE ON AN UNAUTHORIZED INSURER THAT DOES AN ACT OF INSURANCE BUSINESS IN THE STATE.
- (3) A REQUEST FOR A HEARING ON ANY ORDER ISSUED UNDER THIS SECTION DOES NOT STAY THAT PORTION OF THE ORDER THAT REQUIRES THE PHARMACY BENEFITS MANAGER TO CEASE AND DESIST FROM CONDUCT IDENTIFIED IN THE ORDER.
- (4) THE COMMISSIONER MAY FILE A PETITION IN THE CIRCUIT COURT OF ANY COUNTY TO ENFORCE AN ORDER ISSUED UNDER THIS SECTION, WHETHER OR NOT A HEARING HAS BEEN REQUESTED OR, IF REQUESTED, WHETHER OR NOT A HEARING HAS BEEN HELD.
- (5) If the Commissioner prevails in an action brought under this section, the Commissioner may recover, for the use of the State, reasonable attorney's fees and the costs of the action.
- (C) IN ADDITION TO ANY OTHER ENFORCEMENT ACTION TAKEN BY THE COMMISSIONER UNDER THIS SECTION, THE COMMISSIONER MAY IMPOSE A

CIVIL PENALTY NOT EXCEEDING \$10,000 FOR EACH VIOLATION OF THIS SUBTITLE.

(D) THIS SECTION DOES NOT LIMIT ANY OTHER REGULATORY AUTHORITY OF THE COMMISSIONER UNDER THIS ARTICLE.

15–1609.

A PURCHASER MAY NOT ENTER INTO AN AGREEMENT WITH A PHARMACY BENEFITS MANAGER THAT HAS NOT REGISTERED WITH THE COMMISSIONER.

Article - Health - General

19-706.

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

Article - Health Occupations

12-101.

- (m) (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 16 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;
- (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;
- (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 subtitle, 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 Maryland Insurance Commissioner, as required under Section 1 of this Act, if the person:

- (1) registers with the Commissioner on or before July 1, 2009; and
- (2) complies with all other applicable provisions of this Act.

SECTION 3. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2008.

Approved by the Governor, April 24, 2008.