

HOUSE BILL 419

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By: **Delegates Elliott, Ali, Bartlett, Beitzel, Bromwell, Cane, Costa, DeBoy, Frush, George, Norman, Hammen, Hecht, Hubbard, Impallaria, Kach, King, Kipke, Kirk, Krebs, Kullen, McDonough, Mizeur, Montgomery, Morhaim, Nathan-Pulliam, Oaks, Pena-Melnyk, Pendergrass, Proctor, Reznik, Riley, Rudolph, Smigiel, Sophocleus, Sossi, Stukes, Stull, V. Turner, Walkup, Weir, and Weldon**

Introduced and read first time: January 28, 2008

Assigned to: Health and Government Operations

A BILL ENTITLED

1 AN ACT concerning

2 **Pharmacy Benefits Managers - Registration**

3 FOR the purpose of requiring a person to register with the Maryland Insurance
4 Commissioner before the person acts as or represents itself as a pharmacy
5 benefits manager in the State; exempting certain managed care organizations,
6 insurers, nonprofit health service plans, and health maintenance organizations,
7 and affiliates, subsidiaries, or other related entities of certain insurers,
8 nonprofit health service plans, and health maintenance organizations from
9 certain provisions of this Act under certain circumstances; requiring an
10 applicant for registration to file an application on a certain form and pay to the
11 Commissioner a certain fee; requiring the Commissioner to register certain
12 applicants; providing for the expiration and renewal of a registration;
13 prohibiting a pharmacy benefits manager from taking certain actions;
14 authorizing the Commissioner to deny, suspend, or revoke a registration or
15 refuse to renew a registration under certain circumstances and subject to
16 certain hearing provisions; authorizing the Commissioner, if a registration is
17 suspended or revoked, to permit the continued operation of a pharmacy benefits
18 manager for a certain period of time under certain circumstances; requiring a
19 pharmacy benefits manager to register as a third party administrator or a
20 private review agent under certain circumstances; requiring a certain pharmacy
21 benefits manager to pay and adjust claims according to certain statutory
22 requirements; prohibiting an insurer, a nonprofit health service plan, or a
23 health maintenance organization from entering into an agreement with a
24 pharmacy benefits manager that has not registered with the Commissioner;
25 requiring the Commissioner to conduct a certain examination in accordance
26 with certain provisions of law; requiring a pharmacy benefits manager to

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 maintain certain books and records for a certain period and in accordance with
 2 certain standards; requiring the Commissioner to adopt certain regulations on
 3 or before a certain date; providing certain penalties; altering the definition of a
 4 “nonresident pharmacy” to include a pharmacy benefits manager under certain
 5 provisions of law; requiring a nonresident pharmacy to meet certain
 6 requirements; making certain provisions of law applicable to health
 7 maintenance organizations; allowing a certain person to continue to act as a
 8 pharmacy benefits manager without registering with the Commissioner under
 9 certain circumstances; defining certain terms; and generally relating to
 10 regulation and registration of pharmacy benefits managers.

11 BY adding to
 12 Article – Insurance
 13 Section 15–1601 through 15–1613 to be under the new subtitle “Subtitle 16.
 14 Pharmacy Benefits Managers”
 15 Annotated Code of Maryland
 16 (2006 Replacement Volume and 2007 Supplement)

17 BY adding to
 18 Article – Health – General
 19 Section 19–706(ppp)
 20 Annotated Code of Maryland
 21 (2005 Replacement Volume and 2007 Supplement)

22 BY repealing and reenacting, with amendments,
 23 Article – Health Occupations
 24 Section 12–101(m) and 12–403(e) and (f)
 25 Annotated Code of Maryland
 26 (2005 Replacement Volume and 2007 Supplement)

27 BY repealing and reenacting, without amendments,
 28 Article – Health Occupations
 29 Section 12–403(a), (b)(17), (d), and (g)
 30 Annotated Code of Maryland
 31 (2005 Replacement Volume and 2007 Supplement)

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

34 **Article – Insurance**

35 **SUBTITLE 16. PHARMACY BENEFITS MANAGERS.**

36 **15–1601.**

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

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

3 **(2) “PHARMACY BENEFITS MANAGEMENT SERVICES” INCLUDES:**

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

6 **(II) PROCESSING OF PRESCRIPTION DRUG CLAIMS;**

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

9 **(IV) NEGOTIATING OR ENTERING INTO CONTRACTUAL**
10 **ARRANGEMENTS WITH PHARMACIES OR PHARMACISTS.**

11 **(C) “PHARMACY BENEFITS MANAGER” MEANS A PERSON THAT**
12 **PERFORMS PHARMACY BENEFITS MANAGEMENT SERVICES.**

13 **(D) (1) “UTILIZATION REVIEW” HAS THE MEANING STATED IN**
14 **§ 15-10B-01 OF THIS TITLE.**

15 **(2) “UTILIZATION REVIEW” INCLUDES:**

16 **(I) DRUG UTILIZATION MANAGEMENT;**

17 **(II) DRUG UTILIZATION REVIEW SERVICES; AND**

18 **(III) STEP PROTOCOL THERAPY MANAGEMENT.**

19 **15-1602.**

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

23 **(B) THE PROVISIONS OF THIS SUBTITLE DO NOT APPLY TO AN INSURER,**
24 **A NONPROFIT HEALTH SERVICE PLAN, OR A HEALTH MAINTENANCE**
25 **ORGANIZATION OR AN AFFILIATE, SUBSIDIARY, OR OTHER RELATED ENTITY OF**
26 **AN INSURER, A NONPROFIT HEALTH SERVICE PLAN, OR A HEALTH**
27 **MAINTENANCE ORGANIZATION ACTING OR REPRESENTING ITSELF AS A**
28 **PHARMACY BENEFITS MANAGER IF:**

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

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

11 **15-1603.**

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

15 (B) AN APPLICANT FOR REGISTRATION SHALL:

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

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

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

23 **15-1604.**

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

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

28 (1) OTHERWISE IS ENTITLED TO BE REGISTERED;

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

1 **(3) PAYS TO THE COMMISSIONER A RENEWAL FEE SET BY THE**
2 **COMMISSIONER.**

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

6 **15-1605.**

7 **A PHARMACY BENEFITS MANAGER MAY NOT:**

8 **(1) VIOLATE ANY PROVISION OF THIS ARTICLE APPLICABLE TO**
9 **THE PHARMACY BENEFITS MANAGER;**

10 **(2) VIOLATE ANY REGULATION ADOPTED UNDER THIS ARTICLE**
11 **APPLICABLE TO THE PHARMACY BENEFITS MANAGER;**

12 **(3) KNOWINGLY FAIL TO COMPLY WITH ANY ORDER OF THE**
13 **COMMISSIONER;**

14 **(4) OBTAIN OR ATTEMPT TO OBTAIN A REGISTRATION BASED ON**
15 **INACCURATE INFORMATION;**

16 **(5) FRAUDULENTLY OR DECEPTIVELY OBTAIN OR USE A**
17 **REGISTRATION;**

18 **(6) FAIL TO PROTECT THE CONFIDENTIALITY OF MEDICAL**
19 **RECORDS IN ACCORDANCE WITH APPLICABLE STATE AND FEDERAL LAWS; OR**

20 **(7) ACT AS A PHARMACY BENEFITS MANAGER WITHOUT FIRST**
21 **REGISTERING WITH THE COMMISSIONER.**

22 **15-1606.**

23 **(A) SUBJECT TO THE HEARING PROVISIONS OF TITLE 2 OF THIS**
24 **ARTICLE, THE COMMISSIONER MAY DENY, SUSPEND, OR REVOKE A**
25 **REGISTRATION OR REFUSE TO RENEW A REGISTRATION IF THE APPLICANT OR**
26 **REGISTRANT VIOLATES ANY PROVISION OF § 15-1605 OF THIS SUBTITLE.**

27 **(B) IF THE REGISTRATION OF A PHARMACY BENEFITS MANAGER IS**
28 **SUSPENDED OR REVOKED, THE COMMISSIONER, TO PROTECT THE INTERESTS**
29 **OF BENEFICIARIES AND PHARMACIES AND PHARMACISTS, MAY PERMIT THE**
30 **CONTINUED OPERATION OF THE PHARMACY BENEFITS MANAGER FOR A**

1 LIMITED PERIOD, NOT TO EXCEED 60 DAYS, UNDER CONDITIONS AND
2 RESTRICTIONS DETERMINED BY THE COMMISSIONER.

3 **15-1607.**

4 (A) A PHARMACY BENEFITS MANAGER SHALL REGISTER WITH THE
5 COMMISSIONER AS A THIRD PARTY ADMINISTRATOR UNDER TITLE 8, SUBTITLE
6 3 OF THIS ARTICLE IF THE PHARMACY BENEFITS MANAGER:

7 (1) PROCESSES PRESCRIPTION DRUG CLAIMS; OR

8 (2) ADMINISTERS PAYMENTS RELATED TO PRESCRIPTION DRUG
9 CLAIMS.

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

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

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

17 **15-1608.**

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

21 **15-1609.**

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

26 **15-1610.**

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

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

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

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

7 15-1611.

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

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

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

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

18 15-1612.

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

21 15-1613.

22 IN ADDITION TO THE PENALTIES AUTHORIZED BY § 15-1606 OF THIS
23 SUBTITLE, THE COMMISSIONER MAY ASSESS A CIVIL PENALTY NOT EXCEEDING
24 \$10,000 FOR EACH VIOLATION OF THIS SUBTITLE.

25 Article - Health - General

26 19-706.

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

29 Article - Health Occupations

1 12-101.

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

5 (2) **“NONRESIDENT PHARMACY” INCLUDES A PHARMACY**
6 **BENEFITS MANAGER, LOCATED WITHIN OR OUTSIDE THIS STATE, THAT IS**
7 **REGULATED UNDER TITLE 15, SUBTITLE 16 OF THE INSURANCE ARTICLE, IF**
8 **THE PHARMACY BENEFITS MANAGER SHIPS, MAILS, OR DELIVERS DRUGS OR**
9 **DEVICES TO A PERSON IN THIS STATE PURSUANT TO A PRESCRIPTION.**

10 12-403.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

11 (2) On an annual basis and within 30 days after a change of office,
12 corporate officer, or pharmacist, disclose to the Board the location, names, and titles of
13 all principal corporate officers and all pharmacists who are dispensing prescriptions
14 for drugs or devices to persons in this State;

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

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

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

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

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

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

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

32 **AND**

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

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

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

13 (1) registers with the Commissioner on or before July 1, 2009; and

14 (2) complies with all other applicable provisions of this Act.

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