

SENATE BILL 708

J1

9lr2637
CF HB 574

By: **Senators Pugh, Frosh, Jones, and Lenett**

Introduced and read first time: February 6, 2009

Assigned to: Finance

A BILL ENTITLED

1 AN ACT concerning

2 **Prescription Drugs – Evidence–Based Prescriber Education and Outreach**
3 **Program**

4 FOR the purpose of establishing an Evidence–Based Prescriber Education and
5 Outreach Program in the Department of Health and Mental Hygiene;
6 establishing the purpose of the Program; requiring the Department, beginning
7 on a certain date in consultation with certain health occupation boards and
8 subject to certain availability, to work with the University of Maryland School
9 of Pharmacy to develop, implement, and promote the Program; authorizing the
10 Department to contract with the School to administer the Program; requiring
11 the Program to provide certain health care professionals with certain
12 information and education; authorizing the Program to provide the information
13 and education to other health care professionals under certain circumstances;
14 establishing requirements for the informational and educational materials used
15 in the Program; requiring the Department, working with the School, to make
16 certain determinations for individuals conducting outreach and education
17 sessions; authorizing the Department to adopt certain regulations; establishing
18 an Evidence–Based Prescriber Education and Outreach Program Fund;
19 establishing the purpose of and requirements for the Fund; providing that the
20 Fund consists of certain fees and certain other money; providing that the Fund
21 may be used only for certain purposes; requiring the State Treasurer to invest
22 the money of the Fund in a certain manner and to credit certain earnings to the
23 General Fund of the State; providing that expenditures from the Fund may be
24 made only in accordance with the State budget; requiring as of a certain date
25 and annually thereafter certain pharmaceutical manufacturers and labelers to
26 pay a certain fee to the Department; authorizing the Department to reduce the
27 fee for certain pharmaceutical manufacturers and labelers; requiring the
28 Department to deposit all fees collected in the Fund; defining certain terms; and
29 generally relating to an Evidence–Based Prescriber Education and Outreach
30 Program.

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



BY adding to
Article – Health – General
Section 21–2B–01 through 21–2B–03 to be under the new subtitle “Subtitle 2B.
Evidence–Based Prescriber Education and Outreach Program”
Annotated Code of Maryland
(2005 Replacement Volume and 2008 Supplement)

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

Article – Health – General

**SUBTITLE 2B. EVIDENCE–BASED PRESCRIBER EDUCATION AND OUTREACH
PROGRAM.**

21–2B–01.

(A) (1) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE
MEANINGS INDICATED.

(2) “FUND” MEANS THE EVIDENCE–BASED PRESCRIBER
EDUCATION AND OUTREACH PROGRAM FUND.

(3) “LABELER” MEANS A PERSON THAT:

(I) RECEIVES PRESCRIPTION DRUGS OR BIOLOGICAL
PRODUCTS FROM A MANUFACTURER OR WHOLESALE DISTRIBUTOR;

(II) REPACKAGES THE PRESCRIPTION DRUGS OR
BIOLOGICAL PRODUCTS FOR LATER RESALE; AND

(III) HAS A LABELER CODE FROM THE FEDERAL FOOD AND
DRUG ADMINISTRATION UNDER § 207.20 OF TITLE 21 OF THE CODE OF
FEDERAL REGULATIONS.

(4) “PHARMACEUTICAL MANUFACTURER” MEANS A
MANUFACTURER, OR AN AFFILIATE OF A MANUFACTURER, OF PRESCRIPTION
DRUGS OR BIOLOGICAL PRODUCTS.

(5) “PROGRAM” MEANS THE EVIDENCE–BASED PRESCRIBER
EDUCATION AND OUTREACH PROGRAM.

(6) (I) “STATE HEALTH CARE PROGRAM” MEANS A PROGRAM
OR FACILITY SERVING INDIVIDUALS FOR WHOM THE STATE PURCHASES
PRESCRIPTION DRUGS OR PHARMACEUTICAL SERVICES.

1 (II) “STATE HEALTH CARE PROGRAM” INCLUDES THE
2 MEDICAL ASSISTANCE PROGRAM, THE STATE EMPLOYEE AND RETIREE
3 HEALTH AND WELFARE BENEFITS PROGRAM, STATE HOSPITALS, AND
4 CORRECTIONAL FACILITIES.

5 (B) THERE IS AN EVIDENCE-BASED PRESCRIBER EDUCATION AND
6 OUTREACH PROGRAM IN THE DEPARTMENT.

7 (C) THE PURPOSE OF THE PROGRAM IS TO IMPROVE HEALTH
8 OUTCOMES AND REDUCE UNNECESSARY COSTS BY ENSURING THAT HEALTH
9 CARE PROFESSIONALS HAVE BALANCED AND UNBIASED EVIDENCE-BASED
10 INFORMATION READILY AVAILABLE TO SUPPORT THEIR PRESCRIBING
11 DECISIONS.

12 (D) BEGINNING APRIL 1, 2011, THE DEPARTMENT, IN CONSULTATION
13 WITH THE MARYLAND BOARD OF PHYSICIANS AND THE STATE BOARD OF
14 PHARMACY AND SUBJECT TO THE AVAILABILITY OF FUNDS:

15 (1) SHALL WORK WITH THE UNIVERSITY OF MARYLAND SCHOOL
16 OF PHARMACY TO DEVELOP, IMPLEMENT, AND PROMOTE THE PROGRAM; AND

17 (2) MAY CONTRACT WITH THE UNIVERSITY OF MARYLAND
18 SCHOOL OF PHARMACY TO ADMINISTER THE PROGRAM.

19 (E) THE PROGRAM SHALL PROVIDE HEALTH CARE PROFESSIONALS
20 WHO ARE AUTHORIZED BY LAW TO PRESCRIBE OR DISPENSE PRESCRIPTION
21 DRUGS WITH INFORMATION AND EDUCATION:

22 (1) ON THE COMPARATIVE EFFICACY, SAFETY, AND
23 COST-EFFECTIVENESS OF PRESCRIPTION DRUGS; AND

24 (2) PRIMARILY THROUGH IN-PERSON OUTREACH AND
25 EDUCATION SESSIONS, ON A ONE-TO-ONE BASIS WHEN PRACTICABLE, IN THE
26 WORKPLACE OF THE HEALTH CARE PROFESSIONALS.

27 (F) (1) THE PROGRAM SHALL PROVIDE THE INFORMATION AND
28 EDUCATION UNDER SUBSECTION (E) OF THIS SECTION TO HEALTH CARE
29 PROFESSIONALS WHO PARTICIPATE IN, CONTRACT WITH, OR ARE REIMBURSED
30 BY STATE HEALTH CARE PROGRAMS.

31 (2) THE PROGRAM MAY PROVIDE THE INFORMATION AND
32 EDUCATION UNDER SUBSECTION (E) OF THIS SECTION TO OTHER HEALTH CARE
33 PROFESSIONALS AS FUNDING PERMITS OR FOR A FEE.

1 **(G) THE INFORMATIONAL AND EDUCATIONAL MATERIALS USED IN THE**
2 **PROGRAM:**

3 **(1) SHALL BE BASED ON A BALANCED AND COMPREHENSIVE**
4 **REVIEW OF EVIDENCE THAT IS ACCEPTED WITHIN THE PRACTICE OF MEDICINE,**
5 **INCLUDING SCIENTIFIC RESEARCH THAT CONFORMS TO THE GENERALLY**
6 **ACCEPTED STANDARDS OF EXPERIMENTAL DESIGN, DATA COLLECTION,**
7 **ANALYSIS, AND INTERPRETATION; AND**

8 **(2) SHALL AIM TO PROVIDE UNBIASED CONTINUING EDUCATION**
9 **ON THE COMPARATIVE EFFICACY, SAFETY, AND COST-EFFECTIVENESS OF**
10 **PRESCRIPTION DRUGS.**

11 **(H) THE DEPARTMENT, WORKING WITH THE UNIVERSITY OF**
12 **MARYLAND SCHOOL OF PHARMACY, SHALL DETERMINE, FOR INDIVIDUALS**
13 **CONDUCTING OUTREACH AND EDUCATION SESSIONS:**

14 **(1) MINIMUM CLINICAL AND EDUCATIONAL QUALIFICATIONS;**

15 **(2) REQUIRED TRAINING;**

16 **(3) A CODE OF CONDUCT GOVERNING INTERACTIONS WITH**
17 **HEALTH CARE PROFESSIONALS; AND**

18 **(4) CONFLICT OF INTEREST GUIDELINES.**

19 **(I) THE DEPARTMENT MAY ADOPT REGULATIONS TO CARRY OUT THE**
20 **REQUIREMENTS OF THIS SUBTITLE.**

21 **21-2B-02.**

22 **(A) THERE IS AN EVIDENCE-BASED PRESCRIBER EDUCATION AND**
23 **OUTREACH PROGRAM FUND.**

24 **(B) THE PURPOSE OF THE FUND IS TO SUPPORT THE OPERATION OF**
25 **THE PROGRAM.**

26 **(C) THE DEPARTMENT SHALL ADMINISTER THE FUND.**

27 **(D) (1) THE FUND IS A SPECIAL, NONLAPSING FUND THAT IS NOT**
28 **SUBJECT TO § 7-302 OF THE STATE FINANCE AND PROCUREMENT ARTICLE.**

1 (2) THE STATE TREASURER SHALL HOLD THE FUND
2 SEPARATELY, AND THE COMPTROLLER SHALL ACCOUNT FOR THE FUND.

3 (E) THE FUND CONSISTS OF:

4 (1) FEES COLLECTED FROM PHARMACEUTICAL MANUFACTURERS
5 AND LABELERS UNDER § 21-2B-03 OF THIS SUBTITLE;

6 (2) MONEY APPROPRIATED IN THE STATE BUDGET TO THE FUND;
7 AND

8 (3) ANY OTHER MONEY FROM ANY OTHER SOURCE ACCEPTED
9 FOR THE BENEFIT OF THE FUND.

10 (F) THE FUND MAY BE USED ONLY FOR:

11 (1) PRESCRIBER INFORMATION, EDUCATION AND OUTREACH
12 ACTIVITIES, AS PROVIDED UNDER § 21-2B-01 OF THIS SUBTITLE; AND

13 (2) ADMINISTRATION OF THE PROGRAM.

14 (G) (1) THE STATE TREASURER SHALL INVEST THE MONEY OF THE
15 FUND IN THE SAME MANNER AS OTHER STATE MONEY MAY BE INVESTED.

16 (2) ANY INVESTMENT EARNINGS OF THE FUND SHALL BE
17 CREDITED TO THE GENERAL FUND OF THE STATE.

18 (H) EXPENDITURES FROM THE FUND MAY BE MADE ONLY IN
19 ACCORDANCE WITH THE STATE BUDGET.

20 **21-2B-03.**

21 (A) BEGINNING APRIL 1, 2010, AND ANNUALLY THEREAFTER, EACH
22 PHARMACEUTICAL MANUFACTURER AND LABELER DOING BUSINESS IN THE
23 STATE SHALL PAY A FEE OF \$2,500 TO THE DEPARTMENT.

24 (B) THE DEPARTMENT MAY REDUCE THE FEE TO BE PAID UNDER
25 SUBSECTION (A) OF THIS SECTION FOR A PHARMACEUTICAL MANUFACTURER
26 OR LABELER WHOSE VOLUME OF BUSINESS IN THE STATE JUSTIFIES A FEE
27 REDUCTION, AS DETERMINED BY THE DEPARTMENT.

28 (C) THE DEPARTMENT SHALL DEPOSIT ALL FEES COLLECTED UNDER
29 THIS SECTION IN THE FUND ESTABLISHED UNDER § 21-2B-02 OF THIS
30 SUBTITLE.

1 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
2 October 1, 2009.