

HOUSE BILL 574

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9lr0671
CF 9lr2637

By: **Delegates Hubbard, Anderson, Barnes, Barve, Benson, Bobo, Branch, Braveboy, Burns, Carter, V. Clagett, Gaines, Glenn, Gutierrez, Hecht, Holmes, Howard, Hucker, Krysiak, Kullen, Lafferty, Lee, Manno, McHale, McIntosh, Mizeur, Montgomery, Pena-Melnyk, Ramirez, Reznik, Riley, Ross, Taylor, F. Turner, V. Turner, Valderrama, and Weldon**

Introduced and read first time: February 6, 2009

Assigned to: Health and Government Operations

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

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 fee for certain pharmaceutical manufacturers and labelers; requiring the
2 Department to deposit all fees collected in the Fund; defining certain terms; and
3 generally relating to an Evidence-Based Prescriber Education and Outreach
4 Program.

5 BY adding to
6 Article – Health – General
7 Section 21–2B–01 through 21–2B–03 to be under the new subtitle “Subtitle 2B.
8 Evidence–Based Prescriber Education and Outreach Program”
9 Annotated Code of Maryland
10 (2005 Replacement Volume and 2008 Supplement)

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

13 **Article – Health – General**

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

16 **21–2B–01.**

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

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

21 (3) “LABELER” MEANS A PERSON THAT:

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

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

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

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

1 (5) **“PROGRAM” MEANS THE EVIDENCE-BASED PRESCRIBER**
2 **EDUCATION AND OUTREACH PROGRAM.**

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

6 (II) **“STATE HEALTH CARE PROGRAM” INCLUDES THE**
7 **MEDICAL ASSISTANCE PROGRAM, THE STATE EMPLOYEE AND RETIREE**
8 **HEALTH AND WELFARE BENEFITS PROGRAM, STATE HOSPITALS, AND**
9 **CORRECTIONAL FACILITIES.**

10 (B) **THERE IS AN EVIDENCE-BASED PRESCRIBER EDUCATION AND**
11 **OUTREACH PROGRAM IN THE DEPARTMENT.**

12 (C) **THE PURPOSE OF THE PROGRAM IS TO IMPROVE HEALTH**
13 **OUTCOMES AND REDUCE UNNECESSARY COSTS BY ENSURING THAT HEALTH**
14 **CARE PROFESSIONALS HAVE BALANCED AND UNBIASED EVIDENCE-BASED**
15 **INFORMATION READILY AVAILABLE TO SUPPORT THEIR PRESCRIBING**
16 **DECISIONS.**

17 (D) **BEGINNING APRIL 1, 2011, THE DEPARTMENT, IN CONSULTATION**
18 **WITH THE MARYLAND BOARD OF PHYSICIANS AND THE STATE BOARD OF**
19 **PHARMACY AND SUBJECT TO THE AVAILABILITY OF FUNDS:**

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

22 (2) **MAY CONTRACT WITH THE UNIVERSITY OF MARYLAND**
23 **SCHOOL OF PHARMACY TO ADMINISTER THE PROGRAM.**

24 (E) **THE PROGRAM SHALL PROVIDE HEALTH CARE PROFESSIONALS**
25 **WHO ARE AUTHORIZED BY LAW TO PRESCRIBE OR DISPENSE PRESCRIPTION**
26 **DRUGS WITH INFORMATION AND EDUCATION:**

27 (1) **ON THE COMPARATIVE EFFICACY, SAFETY, AND**
28 **COST-EFFECTIVENESS OF PRESCRIPTION DRUGS; AND**

29 (2) **PRIMARILY THROUGH IN-PERSON OUTREACH AND**
30 **EDUCATION SESSIONS, ON A ONE-TO-ONE BASIS WHEN PRACTICABLE, IN THE**
31 **WORKPLACE OF THE HEALTH CARE PROFESSIONALS.**

32 (F) (1) **THE PROGRAM SHALL PROVIDE THE INFORMATION AND**
33 **EDUCATION UNDER SUBSECTION (E) OF THIS SECTION TO HEALTH CARE**

1 PROFESSIONALS WHO PARTICIPATE IN, CONTRACT WITH, OR ARE REIMBURSED
2 BY STATE HEALTH CARE PROGRAMS.

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

6 (G) THE INFORMATIONAL AND EDUCATIONAL MATERIALS USED IN THE
7 PROGRAM:

8 (1) SHALL BE BASED ON A BALANCED AND COMPREHENSIVE
9 REVIEW OF EVIDENCE THAT IS ACCEPTED WITHIN THE PRACTICE OF MEDICINE,
10 INCLUDING SCIENTIFIC RESEARCH THAT CONFORMS TO THE GENERALLY
11 ACCEPTED STANDARDS OF EXPERIMENTAL DESIGN, DATA COLLECTION,
12 ANALYSIS, AND INTERPRETATION; AND

13 (2) SHALL AIM TO PROVIDE UNBIASED CONTINUING EDUCATION
14 ON THE COMPARATIVE EFFICACY, SAFETY, AND COST-EFFECTIVENESS OF
15 PRESCRIPTION DRUGS.

16 (H) THE DEPARTMENT, WORKING WITH THE UNIVERSITY OF
17 MARYLAND SCHOOL OF PHARMACY, SHALL DETERMINE, FOR INDIVIDUALS
18 CONDUCTING OUTREACH AND EDUCATION SESSIONS:

19 (1) MINIMUM CLINICAL AND EDUCATIONAL QUALIFICATIONS;

20 (2) REQUIRED TRAINING;

21 (3) A CODE OF CONDUCT GOVERNING INTERACTIONS WITH
22 HEALTH CARE PROFESSIONALS; AND

23 (4) CONFLICT OF INTEREST GUIDELINES.

24 (I) THE DEPARTMENT MAY ADOPT REGULATIONS TO CARRY OUT THE
25 REQUIREMENTS OF THIS SUBTITLE.

26 21-2B-02.

27 (A) THERE IS AN EVIDENCE-BASED PRESCRIBER EDUCATION AND
28 OUTREACH PROGRAM FUND.

29 (B) THE PURPOSE OF THE FUND IS TO SUPPORT THE OPERATION OF
30 THE PROGRAM.

1 (C) THE DEPARTMENT SHALL ADMINISTER THE FUND.

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

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

6 (E) THE FUND CONSISTS OF:

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

9 (2) MONEY APPROPRIATED IN THE STATE BUDGET TO THE FUND;
10 AND

11 (3) ANY OTHER MONEY FROM ANY OTHER SOURCE ACCEPTED
12 FOR THE BENEFIT OF THE FUND.

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

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

16 (2) ADMINISTRATION OF THE PROGRAM.

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

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

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

23 **21-2B-03.**

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

27 (B) THE DEPARTMENT MAY REDUCE THE FEE TO BE PAID UNDER
28 SUBSECTION (A) OF THIS SECTION FOR A PHARMACEUTICAL MANUFACTURER

1 OR LABELER WHOSE VOLUME OF BUSINESS IN THE STATE JUSTIFIES A FEE
2 REDUCTION, AS DETERMINED BY THE DEPARTMENT.

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

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