

HOUSE BILL 50

J3

8lr0331

(PRE-FILED)

By: **Delegate Montgomery**

Requested: May 24, 2007

Introduced and read first time: January 9, 2008

Assigned to: Health and Government Operations

A BILL ENTITLED

1 AN ACT concerning

2 **Prescription Drugs – Marketing or Promotion – Use of Prescriber Identifying**
3 **Information**

4 FOR the purpose of requiring the Secretary of Health and Mental Hygiene, in
5 consultation with certain licensing boards, to establish a prescriber
6 data-sharing program for a certain purpose; establishing certain requirements
7 for the prescriber data-sharing program; requiring the Secretary, with certain
8 frequency, to update a list of certain prescribers and make the list available to
9 certain persons; authorizing certain persons to obtain or use prescriber
10 identifying information for marketing or promoting a prescription drug only
11 under certain circumstances; requiring a pharmaceutical detailer to disclose
12 certain information to a prescriber under certain circumstances; requiring the
13 Secretary to adopt certain regulations; requiring the Secretary of Budget and
14 Management to prohibit certain persons that participate in, have a contract
15 with, or do business with the State Employee and Retiree Health and Welfare
16 Benefits Program from obtaining or using certain prescriber identifying
17 information for certain purposes; defining certain terms; and generally relating
18 to the use of prescriber identifying information for marketing or promotion of
19 prescription drugs.

20 BY adding to

21 Article – Health – General

22 Section 21–220.1

23 Annotated Code of Maryland

24 (2005 Replacement Volume and 2007 Supplement)

25 BY repealing and reenacting, without amendments,

26 Article – Health – General

27 Section 21–1215

28 Annotated Code of Maryland

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 (2005 Replacement Volume and 2007 Supplement)

2 BY repealing and reenacting, without amendments,
3 Article – State Personnel and Pensions
4 Section 1–101(a) and (m) and 2–501(a) and (b)
5 Annotated Code of Maryland
6 (2004 Replacement Volume and 2007 Supplement)

7 BY adding to
8 Article – State Personnel and Pensions
9 Section 2–502.2
10 Annotated Code of Maryland
11 (2004 Replacement Volume and 2007 Supplement)

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

14 **Article – Health – General**

15 **21–220.1.**

16 (A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE
17 MEANINGS INDICATED.

18 (2) “CARRIER” MEANS:

19 (I) AN INSURER;

20 (II) A NONPROFIT HEALTH SERVICE PLAN;

21 (III) A HEALTH MAINTENANCE ORGANIZATION;

22 (IV) A DENTAL PLAN ORGANIZATION;

23 (V) A THIRD PARTY ADMINISTRATOR; OR

24 (VI) ANY OTHER PERSON THAT PROVIDES HEALTH BENEFIT
25 PLANS SUBJECT TO REGULATION BY THE STATE.

26 (3) “DATA TRANSFER INTERMEDIARY” MEANS AN ENTITY THAT
27 PROVIDES THE INFRASTRUCTURE THAT CONNECTS THE COMPUTER SYSTEMS
28 OR OTHER ELECTRONIC DEVICES USED BY PRESCRIBERS, PHARMACIES,
29 HEALTH CARE FACILITIES, PHARMACY BENEFIT MANAGERS, AND CARRIERS, OR
30 AGENTS AND CONTRACTORS OF PRESCRIBERS, PHARMACIES, HEALTH CARE
31 FACILITIES, PHARMACY BENEFIT MANAGERS, AND CARRIERS, TO FACILITATE

1 THE SECURE TRANSMISSION OF AN INDIVIDUAL'S PRESCRIPTION DRUG ORDER,
2 REFILL, AUTHORIZATION REQUEST, CLAIM, PAYMENT, OR OTHER
3 PRESCRIPTION DRUG INFORMATION.

4 (4) "IDENTIFYING INFORMATION" MEANS THE NAME, DATE OF
5 BIRTH, EDUCATIONAL BACKGROUND, SPECIALTY, ADDRESS, OR OTHER
6 INFORMATION THAT IDENTIFIES A PRESCRIBER.

7 (5) "MARKETING" MEANS ADVERTISING, PROMOTION, OR ANY
8 OTHER ACTIVITY THAT IS INTENDED TO BE USED OR IS USED TO:

9 (I) INFLUENCE SALES OR THE MARKET SHARE OF A
10 PRESCRIPTION DRUG;

11 (II) INFLUENCE OR EVALUATE THE PRESCRIBING
12 BEHAVIOR OF AN INDIVIDUAL HEALTH CARE PRACTITIONER FOR THE PURPOSE
13 OF PROMOTING A PRESCRIPTION DRUG;

14 (III) MARKET PRESCRIPTION DRUGS TO PATIENTS; OR

15 (IV) EVALUATE THE EFFECTIVENESS OF A PROFESSIONAL
16 PHARMACEUTICAL DETAILING SALES FORCE.

17 (6) (I) "PROMOTION" OR "PROMOTE" MEANS ANY ACTIVITY OR
18 PRODUCT THE PURPOSE OF WHICH IS TO ADVERTISE OR PUBLICIZE A
19 PRESCRIPTION DRUG.

20 (II) "PROMOTION" OR "PROMOTE" INCLUDES:

21 1. A BROCHURE;

22 2. A MEDIA ADVERTISEMENT OR ANNOUNCEMENT;

23 3. A POSTER;

24 4. A FREE SAMPLE;

25 5. A DETAILING VISIT; OR

26 6. A PERSONAL APPEARANCE AT A MEETING OF
27 PRESCRIBERS.

28 (B) (1) THE SECRETARY, IN CONSULTATION WITH THE APPROPRIATE
29 HEALTH OCCUPATION LICENSING BOARDS, SHALL ESTABLISH A PRESCRIBER

1 DATA-SHARING PROGRAM TO ALLOW A PRESCRIBER TO GIVE CONSENT FOR THE
2 PRESCRIBER'S IDENTIFYING INFORMATION TO BE USED FOR THE PURPOSES
3 DESCRIBED IN SUBSECTION (D) OF THIS SECTION.

4 (2) THE PRESCRIBER DATA-SHARING PROGRAM SHALL:

5 (I) SOLICIT THE PRESCRIBER'S CONSENT ON LICENSING
6 APPLICATIONS AND RENEWAL FORMS; AND

7 (II) PROVIDE A METHOD FOR A PRESCRIBER TO REVOKE
8 CONSENT.

9 (C) AT LEAST TWICE A YEAR, THE SECRETARY SHALL:

10 (1) UPDATE THE LIST OF PRESCRIBERS WHO HAVE CONSENTED
11 TO SHARING THEIR IDENTIFYING INFORMATION; AND

12 (2) MAKE THE LIST AVAILABLE TO THE PERSONS DESCRIBED IN
13 SUBSECTION (D) OF THIS SECTION.

14 (D) A CARRIER, PHARMACY, PHARMACY BENEFITS MANAGER,
15 PHARMACEUTICAL MANUFACTURER, OR DATA TRANSFER INTERMEDIARY OR
16 THE AGENT OF A CARRIER, PHARMACY, PHARMACY BENEFITS MANAGER,
17 PHARMACEUTICAL MANUFACTURER, OR DATA TRANSFER INTERMEDIARY MAY
18 OBTAIN OR USE PRESCRIBER IDENTIFYING INFORMATION FOR MARKETING OR
19 PROMOTING A PRESCRIPTION DRUG ONLY IF:

20 (1) A PRESCRIBER HAS PROVIDED CONSENT FOR THE USE OF THE
21 PRESCRIBER'S IDENTIFYING INFORMATION, AS PROVIDED IN SUBSECTION (B)
22 OF THIS SECTION; AND

23 (2) THE PERSON USING THE INFORMATION COMPLIES WITH THE
24 DISCLOSURE REQUIREMENTS IN SUBSECTION (E) OF THIS SECTION.

25 (E) WHEN A PERSON DESCRIBED IN SUBSECTION (D) OF THIS SECTION
26 ENGAGES IN MARKETING OR PROMOTING A PRESCRIPTION DRUG DIRECTLY TO
27 A PRESCRIBER, THE PERSON SHALL DISCLOSE TO THE PRESCRIBER:

28 (1) EVIDENCE-BASED INFORMATION, CERTIFIED BY THE
29 SECRETARY, DESCRIBING:

30 (I) THE SPECIFIC RISKS AND HEALTH BENEFITS OF USING
31 THE PRESCRIPTION DRUG, INCLUDING THE TYPES OF PATIENTS MOST AT RISK
32 AND MOST LIKELY TO BENEFIT FROM THE PRESCRIPTION DRUG; AND

1 **(II) THE SPECIFIC RISKS AND HEALTH BENEFITS OF USING**
2 **OTHER DRUGS, INCLUDING DRUGS AVAILABLE OVER THE COUNTER, TO TREAT**
3 **THE SAME CONDITION OR DISEASE; AND**

4 **(2) THE VARIATION IN COST AMONG THE DRUG TREATMENT**
5 **OPTIONS USED TO TREAT THE CONDITION OR DISEASE.**

6 **(F) THE SECRETARY SHALL ADOPT REGULATIONS TO IMPLEMENT THE**
7 **REQUIREMENTS OF THIS SECTION, INCLUDING REQUIREMENTS FOR:**

8 **(1) THE PRESCRIBER DATA-SHARING PROGRAM; AND**

9 **(2) CERTIFICATION OF EVIDENCE-BASED INFORMATION FOR THE**
10 **PURPOSES OF SUBSECTION (E)(1) OF THIS SECTION.**

11 21-1215.

12 (a) This section does not apply to a violation of § 21-220(b)(4) of this title.

13 (b) A person who violates any provision of Subtitle 2 of this title or any
14 regulation adopted under Subtitle 2 of this title is guilty of a misdemeanor and on
15 conviction is subject to:

16 (1) A fine not exceeding \$10,000 or imprisonment not exceeding 1 year
17 or both; or

18 (2) If the person has been convicted once of violating Subtitle 2 of this
19 title, a fine not exceeding \$25,000 or imprisonment not exceeding 3 years or both.

20 (c) In addition to any criminal penalties imposed under this section, a person
21 who violates any provision of Subtitle 2 of this title, any rule or regulation adopted
22 under Subtitle 2 of this title, or any term, condition, or limitation of any license or
23 registration issued under Subtitle 2 of this title:

24 (1) Is subject to a civil penalty not exceeding \$5,000, in an action in
25 any District Court; and

26 (2) May be enjoined from continuing the violation.

27 (d) Each day on which a violation occurs is a separate violation under this
28 section.

29 **Article - State Personnel and Pensions**

30 1-101.

1 (a) In this Division I of this article the following words have the meanings
2 indicated.

3 (m) "Secretary" means the Secretary of Budget and Management.

4 2-501.

5 (a) In this subtitle the following terms have the meanings indicated.

6 (b) "Program" means the State Employee and Retiree Health and Welfare
7 Benefits Program.

8 **2-502.2.**

9 (A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE
10 MEANINGS INDICATED.

11 (2) "CARRIER" MEANS:

12 (I) AN INSURER;

13 (II) A NONPROFIT HEALTH SERVICE PLAN;

14 (III) A HEALTH MAINTENANCE ORGANIZATION;

15 (IV) A DENTAL PLAN ORGANIZATION;

16 (V) A THIRD PARTY ADMINISTRATOR; OR

17 (VI) ANY OTHER PERSON THAT PROVIDES HEALTH BENEFIT
18 PLANS SUBJECT TO REGULATION BY THE STATE.

19 (3) "DATA TRANSFER INTERMEDIARY" MEANS AN ENTITY THAT
20 PROVIDES THE INFRASTRUCTURE THAT CONNECTS THE COMPUTER SYSTEMS
21 OR OTHER ELECTRONIC DEVICES USED BY PRESCRIBERS, PHARMACIES,
22 HEALTH CARE FACILITIES, PHARMACY BENEFIT MANAGERS, AND CARRIERS, OR
23 AGENTS AND CONTRACTORS OF PRESCRIBERS, PHARMACIES, HEALTH CARE
24 FACILITIES, PHARMACY BENEFIT MANAGERS, AND CARRIERS, TO FACILITATE
25 THE SECURE TRANSMISSION OF AN INDIVIDUAL'S PRESCRIPTION DRUG ORDER,
26 REFILL, AUTHORIZATION REQUEST, CLAIM, PAYMENT, OR OTHER
27 PRESCRIPTION DRUG INFORMATION.

1 (4) **“IDENTIFYING INFORMATION” MEANS THE NAME, DATE OF**
2 **BIRTH, EDUCATIONAL BACKGROUND, SPECIALTY, ADDRESS, OR OTHER**
3 **INFORMATION THAT IDENTIFIES A PRESCRIBER.**

4 (5) **“MARKETING” MEANS ADVERTISING, PROMOTION, OR ANY**
5 **OTHER ACTIVITY THAT IS INTENDED TO BE USED OR IS USED TO:**

6 (I) **INFLUENCE SALES OR THE MARKET SHARE OF A**
7 **PRESCRIPTION DRUG;**

8 (II) **INFLUENCE OR EVALUATE THE PRESCRIBING BEHAVIOR**
9 **OF AN INDIVIDUAL HEALTH CARE PRACTITIONER FOR THE PURPOSE OF**
10 **PROMOTING A PRESCRIPTION DRUG;**

11 (III) **MARKET PRESCRIPTION DRUGS TO PATIENTS; OR**

12 (IV) **EVALUATE THE EFFECTIVENESS OF A PROFESSIONAL**
13 **PHARMACEUTICAL DETAILING SALES FORCE.**

14 (6) (I) **“PROMOTION” OR “PROMOTE” MEANS ANY ACTIVITY OR**
15 **PRODUCT THE PURPOSE OF WHICH IS TO ADVERTISE OR PUBLICIZE A**
16 **PRESCRIPTION DRUG.**

17 (II) **“PROMOTION” OR “PROMOTE” INCLUDES:**

18 1. **A BROCHURE;**

19 2. **A MEDIA ADVERTISEMENT OR ANNOUNCEMENT;**

20 3. **A POSTER;**

21 4. **A FREE SAMPLE;**

22 5. **A DETAILING VISIT; OR**

23 6. **A PERSONAL APPEARANCE AT A MEETING OF**
24 **PRESCRIBERS.**

25 (B) **THE SECRETARY SHALL PROHIBIT A CARRIER, PHARMACY,**
26 **PHARMACY BENEFITS MANAGER, PHARMACEUTICAL MANUFACTURER, OR DATA**
27 **TRANSFER INTERMEDIARY OR THE AGENT OF A CARRIER, PHARMACY,**
28 **PHARMACY BENEFITS MANAGER, PHARMACEUTICAL MANUFACTURER, OR DATA**
29 **TRANSFER INTERMEDIARY THAT PARTICIPATES IN, HAS A CONTRACT WITH, OR**
30 **DOES BUSINESS WITH THE PROGRAM FROM OBTAINING OR USING PRESCRIBER**

1 **IDENTIFYING INFORMATION FOR MARKETING OR PROMOTING A PRESCRIPTION**
2 **DRUG.**

3 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
4 October 1, 2008.