
By: **Delegate Kullen**

Introduced and read first time: February 10, 2006

Assigned to: Health and Government Operations

A BILL ENTITLED

1 AN ACT concerning

2 **Prescription Drug Monitoring Program**

3 FOR the purpose of establishing a certain Prescription Drug Monitoring Program
4 within the Department of Health and Mental Hygiene; establishing the powers
5 and duties of the Secretary of Health and Mental Hygiene under the Program;
6 creating a certain Advisory Board on Prescription Drug Monitoring to assist in
7 the design, implementation, and evaluation of the Program; establishing the
8 chair, the terms of the members, and the responsibilities of the Board; creating
9 a multidisciplinary consultation team to assist in the interpretation of
10 prescription monitoring data; requiring dispensers to submit electronically
11 certain information to the Program except in certain circumstances; making
12 prescription monitoring data confidential except under certain circumstances;
13 authorizing certain agencies and persons to obtain access to prescription
14 monitoring data under certain circumstances; establishing immunity from civil
15 liability for certain agencies and persons relating to the operation and use of the
16 Program; providing for education and training relating to the Program;
17 establishing penalties for violations of the requirements of the Program;
18 defining certain terms; and generally relating to the creation and operation of
19 the Prescription Drug Monitoring Program.

20 BY adding to

21 Article - Health - General

22 Section 21-2A-01 through 21-2A-09, inclusive, to be under the new subtitle

23 "Subtitle 2A. Prescription Drug Monitoring Program"

24 Annotated Code of Maryland

25 (2005 Replacement Volume and 2005 Supplement)

26 **Preamble**

27 WHEREAS, Thousands of Marylanders suffer from chronic pain and other
28 conditions that make access to pain medications and other pharmaceutical therapies
29 necessary and beneficial; and

1 WHEREAS, Increasing numbers of Maryland adults and adolescents are
2 engaging in prescription drug abuse and diversion to the detriment of their health
3 and welfare; and

4 WHEREAS, Maryland should have a Prescription Drug Monitoring Program
5 that supports the lawful use of controlled substances without interfering with
6 legitimate professional practice and patient care; and

7 WHEREAS, A Prescription Drug Monitoring Program should assist health care
8 professionals and law enforcement professionals in the identification, treatment, and
9 prevention of prescription drug abuse and in the identification and investigation of
10 unlawful prescription drug diversion; and

11 WHEREAS, Data concerning monitored prescription drugs under a Prescription
12 Drug Monitoring Program would be available for research purposes, including
13 research about the effects of the Prescription Drug Monitoring Program itself; now,
14 therefore,

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

17 **Article - Health - General**

18 **SUBTITLE 2A. PRESCRIPTION DRUG MONITORING PROGRAM.**

19 21-2A-01.

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

22 (B) "AUTHORIZED RECIPIENT" MEANS:

23 (1) A DISPENSER;

24 (2) A PRESCRIBER;

25 (3) A FEDERAL LAW ENFORCEMENT AGENCY;

26 (4) A STATE OR LOCAL LAW ENFORCEMENT AGENCY;

27 (5) A LICENSING ENTITY;

28 (6) THE MARYLAND MEDICAL AND PHARMACEUTICAL ASSISTANCE
29 PROGRAMS;

30 (7) A PATIENT WITH RESPECT TO INFORMATION ABOUT THE PATIENT;
31 OR

32 (8) ANY PERSON UNDER CONTRACT WITH THE DEPARTMENT
33 CONCERNING THE OPERATION OF THE PROGRAM.

1 (C) "BOARD" MEANS THE ADVISORY BOARD ON PRESCRIPTION DRUG
2 MONITORING.

3 (D) (1) "DISPENSER" MEANS A PERSON WHO DISPENSES A MONITORED
4 PRESCRIPTION DRUG TO A PATIENT OR THE PATIENT'S AGENT IN THE STATE.

5 (2) "DISPENSER" INCLUDES A PERSON OPERATING BY MAIL OR OTHER
6 MEANS FROM A PLACE OF BUSINESS OUTSIDE THE STATE.

7 (3) "DISPENSER" DOES NOT INCLUDE A LICENSED HOSPITAL PHARMACY
8 THAT DISPENSES A MONITORED PRESCRIPTION DRUG FOR INPATIENT HOSPITAL
9 CARE.

10 (E) "DISPENSES" HAS THE MEANING STATED IN § 12-101 OF THE HEALTH
11 OCCUPATIONS ARTICLE.

12 (F) "DRUG OF CONCERN" MEANS A PRESCRIPTION DRUG THAT:

13 (1) DOES NOT CONTAIN A SUBSTANCE LISTED IN SCHEDULE II
14 THROUGH SCHEDULE IV; AND

15 (2) IS DETERMINED BY THE SECRETARY TO PRESENT AN EMERGING
16 THREAT IN THE STATE BECAUSE OF INCREASING ABUSE OR DIVERSION.

17 (G) "FEDERAL LAW ENFORCEMENT AGENCY" MEANS ANY ENTITY WITHIN THE
18 UNITED STATES DEPARTMENT OF JUSTICE, INCLUDING:

19 (1) THE DRUG ENFORCEMENT ADMINISTRATION;

20 (2) THE FEDERAL BUREAU OF INVESTIGATION; AND

21 (3) A UNITED STATES ATTORNEY'S OFFICE.

22 (H) "LICENSING ENTITY" MEANS AN ENTITY AUTHORIZED UNDER THE
23 HEALTH OCCUPATIONS ARTICLE TO LICENSE, REGULATE, OR DISCIPLINE A
24 PRESCRIBER OR DISPENSER.

25 (I) "MONITORED PRESCRIPTION DRUG" MEANS A PRESCRIPTION DRUG THAT:

26 (1) CONTAINS A SUBSTANCE LISTED IN SCHEDULE II THROUGH
27 SCHEDULE IV; OR

28 (2) IS A DRUG OF CONCERN.

29 (J) "PRESCRIBER" MEANS A LICENSED HEALTH CARE PROFESSIONAL WHO IS
30 AUTHORIZED BY LAW TO PRESCRIBE A MONITORED PRESCRIPTION DRUG.

31 (K) "PRESCRIPTION DRUG" HAS THE MEANING STATED IN § 21-201 OF THIS
32 TITLE.

1 (L) "PRESCRIPTION MONITORING DATA" MEANS THE INFORMATION
2 SUBMITTED TO THE PROGRAM.

3 (M) "PROGRAM" MEANS THE PRESCRIPTION DRUG MONITORING PROGRAM
4 ESTABLISHED UNDER THIS SUBTITLE.

5 (N) "SCHEDULE II" MEANS THE LIST OF CONTROLLED DANGEROUS
6 SUBSTANCES SET FORTH IN § 5-403 OF THE CRIMINAL LAW ARTICLE.

7 (O) "SCHEDULE III" MEANS THE LIST OF CONTROLLED DANGEROUS
8 SUBSTANCES SET FORTH IN § 5-404 OF THE CRIMINAL LAW ARTICLE.

9 (P) "SCHEDULE IV" MEANS THE LIST OF CONTROLLED DANGEROUS
10 SUBSTANCES SET FORTH IN § 5-405 OF THE CRIMINAL LAW ARTICLE.

11 (Q) "STATE OR LOCAL LAW ENFORCEMENT AGENCY" MEANS:

12 (1) A STATE, COUNTY, OR MUNICIPAL POLICE DEPARTMENT OR AGENCY;

13 (2) A SHERIFF'S OFFICE;

14 (3) A STATE'S ATTORNEY'S OFFICE; OR

15 (4) THE OFFICE OF THE ATTORNEY GENERAL.

16 21-2A-02.

17 (A) THE DEPARTMENT SHALL ESTABLISH AND MAINTAIN, IN CONSULTATION
18 WITH THE BOARD, A PRESCRIPTION DRUG MONITORING PROGRAM THAT
19 ELECTRONICALLY COLLECTS AND STORES DATA CONCERNING MONITORED
20 PRESCRIPTION DRUGS.

21 (B) THE SECRETARY MAY:

22 (1) ASSIGN RESPONSIBILITY FOR THE OPERATION OF THE PROGRAM TO
23 ANY UNIT IN THE DEPARTMENT; AND

24 (2) CONTRACT WITH ANY QUALIFIED PERSON AS THE SECRETARY
25 DEEMS NECESSARY FOR THE EFFICIENT AND ECONOMICAL OPERATION OF THE
26 PROGRAM.

27 (C) THE SECRETARY, IN CONSULTATION WITH THE BOARD, SHALL ADOPT
28 REGULATIONS TO CARRY OUT THIS SUBTITLE.

29 (D) THE REGULATIONS ADOPTED BY THE SECRETARY SHALL:

30 (1) PROMOTE A BALANCED USE OF PRESCRIPTION MONITORING DATA
31 TO ASSIST APPROPRIATE LAW ENFORCEMENT ACTIVITIES WHILE PRESERVING THE
32 PROFESSIONAL PRACTICE OF HEALTH CARE PROVIDERS AND THE ACCESS OF
33 PATIENTS TO OPTIMAL PHARMACEUTICAL CARE;

1 (2) IDENTIFY THE CIRCUMSTANCES UNDER WHICH PRESCRIPTION
2 MONITORING DATA ARE PROVIDED TO AN AUTHORIZED RECIPIENT, WITH SUCH
3 CIRCUMSTANCES TO PARALLEL AS CLOSELY AS IS APPROPRIATE AN AUTHORIZED
4 RECIPIENT'S AUTHORITY TO ACCESS SIMILAR CONFIDENTIAL INFORMATION UNDER
5 CURRENT FEDERAL AND STATE LAWS AND REGULATIONS;

6 (3) IDENTIFY THE CIRCUMSTANCES UNDER WHICH AN AUTHORIZED
7 RECIPIENT MAY DISCLOSE PRESCRIPTION MONITORING DATA PROVIDED BY THE
8 PROGRAM;

9 (4) IDENTIFY THE CIRCUMSTANCES UNDER WHICH A FEDERAL LAW
10 ENFORCEMENT AGENCY, A STATE OR LOCAL LAW ENFORCEMENT AGENCY, OR A
11 LICENSING ENTITY THAT HAS RECEIVED PRESCRIPTION MONITORING DATA SHALL
12 CONSULT WITH THE MULTIDISCIPLINARY CONSULTATION TEAM ESTABLISHED
13 UNDER § 21-2A-04 OF THIS SUBTITLE ABOUT THE INTERPRETATION OF THE DATA;

14 (5) PROMOTE APPROPRIATE ACCESS TO PRESCRIPTION MONITORING
15 DATA BY DISPENSERS AND PRESCRIBERS TO HELP PREVENT SUBSTANCE ABUSE AND
16 PRESCRIPTION DRUG DIVERSION;

17 (6) IDENTIFY THE MECHANISM BY WHICH A PRESCRIPTION DRUG IS
18 IDENTIFIED AS A DRUG OF CONCERN;

19 (7) ENSURE THAT THE PROGRAM IS DESIGNED TO:

20 (I) MINIMIZE, TO THE FULLEST EXTENT POSSIBLE, THE BURDEN
21 ON DISPENSERS IN THEIR COMPLIANCE WITH THE REQUIREMENTS OF THIS
22 SUBTITLE; AND

23 (II) PROMOTE SUBMISSION OF PRESCRIPTION MONITORING DATA
24 IN A MANNER COMPATIBLE WITH EXISTING DATA SUBMISSION PRACTICES OF
25 DISPENSERS; AND

26 (8) ENSURE, TO THE FULLEST EXTENT POSSIBLE, THAT PATIENT
27 CONFIDENTIALITY IS PROTECTED.

28 21-2A-03.

29 (A) THERE IS AN ADVISORY BOARD ON PRESCRIPTION DRUG MONITORING IN
30 THE DEPARTMENT.

31 (B) THE BOARD CONSISTS OF THE FOLLOWING 15 MEMBERS:

32 (1) THE ATTORNEY GENERAL OR THE ATTORNEY GENERAL'S DESIGNEE;

33 (2) THE SECRETARY OR THE SECRETARY'S DESIGNEE;

34 (3) THE PRESIDENT OF THE MARYLAND BOARD OF PHARMACY OR THE
35 PRESIDENT'S DESIGNEE;

1 (4) THE CHAIRMAN OF THE MARYLAND BOARD OF PHYSICIANS OR THE
2 CHAIRMAN'S DESIGNEE;

3 (5) THE CHAIRMAN OF THE MARYLAND HEALTH CARE COMMISSION OR
4 THE CHAIRMAN'S DESIGNEE;

5 (6) TWO PHYSICIANS WITH EXPERTISE IN PHYSICAL MEDICINE AND
6 REHABILITATION AND SUBSTANCE ABUSE AND ADDICTION TREATMENT, APPOINTED
7 BY THE SECRETARY AFTER CONSULTATION WITH THE MEDICAL AND CHIRURGICAL
8 FACULTY OF MARYLAND, THE MARYLAND STATE MEDICAL SOCIETY;

9 (7) TWO PHARMACISTS WHO REPRESENT THE PERSPECTIVE OF
10 INDEPENDENT AND CHAIN PHARMACIES AND PHARMACISTS, APPOINTED BY THE
11 SECRETARY AFTER CONSULTATION WITH THE MARYLAND PHARMACISTS
12 ASSOCIATION, THE MARYLAND ASSOCIATION OF CHAIN DRUG STORES, EPIC
13 PHARMACIES, AND ANY OTHER APPROPRIATE ORGANIZATION;

14 (8) A FEDERAL LAW ENFORCEMENT OFFICIAL, APPOINTED BY THE
15 SECRETARY AFTER CONSULTATION WITH THE DRUG ENFORCEMENT
16 ADMINISTRATION OF THE UNITED STATES DEPARTMENT OF JUSTICE;

17 (9) A STATE LAW ENFORCEMENT OFFICIAL, APPOINTED BY THE
18 SECRETARY AFTER CONSULTATION WITH THE MARYLAND STATE POLICE;

19 (10) A LOCAL LAW ENFORCEMENT OFFICIAL, APPOINTED BY THE
20 SECRETARY AFTER CONSULTATION WITH THE MARYLAND CHIEFS OF POLICE
21 ASSOCIATION;

22 (11) A PROSECUTOR, APPOINTED BY THE SECRETARY AFTER
23 CONSULTATION WITH THE MARYLAND STATE'S ATTORNEYS ASSOCIATION; AND

24 (12) TWO MARYLAND CITIZENS WHO REPRESENT THE PERSPECTIVE OF
25 PAIN PATIENTS, APPOINTED BY THE SECRETARY FROM A LIST SUBMITTED BY THE
26 MARYLAND PAIN INITIATIVE.

27 (C) THE SECRETARY SHALL DESIGNATE THE CHAIR OF THE BOARD.

28 (D) (1) THE TERM OF A MEMBER APPOINTED BY THE SECRETARY IS 3 YEARS.

29 (2) IF A VACANCY OCCURS DURING THE TERM OF AN APPOINTED
30 MEMBER, THE SECRETARY SHALL APPOINT A SUCCESSOR WHO SHALL SERVE UNTIL
31 THE TERM EXPIRES.

32 (E) THE BOARD SHALL:

33 (1) MEET NOT FEWER THAN THREE TIMES ANNUALLY;

34 (2) MAKE RECOMMENDATIONS TO THE SECRETARY REGARDING THE
35 DESIGN AND IMPLEMENTATION OF A PRESCRIPTION MONITORING PROGRAM, IN

1 ACCORDANCE WITH THE PROVISIONS OF THIS SUBTITLE, INCLUDING
2 RECOMMENDATIONS ABOUT:

3 (I) REGULATIONS AND THE NEED FOR ANY FURTHER
4 LEGISLATION CONCERNING THE PROGRAM; AND

5 (II) SOURCES OF FUNDING, INCLUDING GRANT FUNDS UNDER THE
6 HAROLD ROGERS PRESCRIPTION DRUG MONITORING PROGRAM AND OTHER
7 FEDERAL OR STATE PROGRAMS;

8 (3) PROVIDE ANNUALLY TO THE GOVERNOR AND THE GENERAL
9 ASSEMBLY AN ANALYSIS OF THE IMPACT OF THE PROGRAM ON PATIENT ACCESS TO
10 PHARMACEUTICAL CARE AND ON CURBING PRESCRIPTION DRUG DIVERSION IN THE
11 STATE, INCLUDING ANY RECOMMENDATIONS RELATED TO MODIFICATION OR
12 CONTINUATION OF THE PROGRAM; AND

13 (4) PROVIDE ONGOING ADVICE AND CONSULTATION ON THE
14 IMPLEMENTATION AND OPERATION OF THE PROGRAM, INCLUDING
15 RECOMMENDATIONS REGARDING:

16 (I) CHANGES IN THE PROGRAM TO REFLECT ADVANCES IN
17 TECHNOLOGY AND BEST PRACTICES IN THE FIELD OF ELECTRONIC HEALTH
18 RECORDS AND ELECTRONIC PRESCRIPTION MONITORING;

19 (II) EMERGING DRUGS OF CONCERN THAT SHOULD BE IDENTIFIED
20 AS MONITORED PRESCRIPTION DRUGS; AND

21 (III) THE DESIGN AND IMPLEMENTATION OF AN ONGOING
22 EVALUATION COMPONENT OF THE PROGRAM.

23 21-2A-04.

24 (A) THE SECRETARY SHALL APPOINT A MULTIDISCIPLINARY CONSULTATION
25 TEAM WITHIN THE PROGRAM.

26 (B) THE MULTIDISCIPLINARY CONSULTATION TEAM SHALL CONSIST OF:

27 (1) PROGRAM STAFF;

28 (2) MEMBERS OF THE BOARD; AND

29 (3) ANY CONSULTANTS THAT THE SECRETARY DETERMINES WILL
30 PROVIDE BROAD EXPERIENCE IN PAIN MANAGEMENT, SUBSTANCE ABUSE, AND
31 PRESCRIPTION DRUG DIVERSION.

32 (C) IN ACCORDANCE WITH REGULATION, THE MULTIDISCIPLINARY
33 CONSULTATION TEAM SHALL ASSIST A FEDERAL LAW ENFORCEMENT AGENCY, A
34 STATE OR LOCAL LAW ENFORCEMENT AGENCY, OR A LICENSING ENTITY THAT HAS
35 RECEIVED PRESCRIPTION MONITORING DATA FROM THE PROGRAM IN
36 INTERPRETING THE DATA AND CONSIDERING WHETHER THE DATA, IN THE CONTEXT

1 OF THE NATURE OF A PRESCRIBER'S OR A DISPENSER'S PRACTICE, A PATIENT'S
2 MEDICAL CONDITION, OR ANY OTHER RELEVANT FACTS, SUGGEST THE NEED FOR
3 FURTHER INVESTIGATION.

4 21-2A-05.

5 (A) FOR EACH MONITORED PRESCRIPTION DRUG THAT IS DISPENSED, A
6 DISPENSER SHALL SUBMIT TO THE PROGRAM INFORMATION SPECIFIED BY THE
7 SECRETARY, INCLUDING:

8 (1) A PATIENT IDENTIFIER;

9 (2) THE PRESCRIPTION DRUG DISPENSED;

10 (3) THE DATE OF DISPENSING;

11 (4) THE QUANTITY DISPENSED;

12 (5) THE PRESCRIBER;

13 (6) THE PHARMACY FROM WHICH THE DRUG IS DISPENSED; AND

14 (7) THE PRESCRIBER'S DIAGNOSIS CODE, IF SUCH CODE IS PART OF THE
15 ELECTRONIC RECORD CREATED BY THE DISPENSER.

16 (B) EXCEPT AS PROVIDED IN SUBSECTION (C) OF THIS SECTION, A DISPENSER
17 SHALL SUBMIT PRESCRIPTION MONITORING DATA TO THE PROGRAM BY
18 ELECTRONIC SUBMISSION.

19 (C) THE PROGRAM, FOR GOOD CAUSE SHOWN, MAY AUTHORIZE A DISPENSER
20 TO:

21 (1) SUBMIT PRESCRIPTION MONITORING DATA BY AN ALTERNATIVE
22 FORM OF SUBMISSION; OR

23 (2) OMIT ONE OR MORE ELEMENTS OF PRESCRIPTION MONITORING
24 DATA.

25 21-2A-06.

26 (A) PRESCRIPTION MONITORING DATA:

27 (1) ARE CONFIDENTIAL;

28 (2) ARE NOT PUBLIC RECORD; AND

29 (3) EXCEPT AS PROVIDED IN SUBSECTIONS (B) AND (D) OF THIS SECTION
30 OR AS OTHERWISE PROVIDED BY LAW, MAY NOT BE DISCLOSED TO ANY PERSON.

31 (B) THE PROGRAM MAY, IN ACCORDANCE WITH REGULATION, DISCLOSE
32 PRESCRIPTION MONITORING DATA TO AN AUTHORIZED RECIPIENT.

1 (C) EXCEPT AS PROVIDED BY REGULATION, AN AUTHORIZED RECIPIENT WHO
2 RECEIVES PRESCRIPTION MONITORING DATA FROM THE PROGRAM MAY NOT
3 DISCLOSE THE DATA.

4 (D) THE PROGRAM MAY DISCLOSE PRESCRIPTION MONITORING DATA AFTER
5 REDACTION OF ALL INFORMATION THAT COULD IDENTIFY A PATIENT, PRESCRIBER,
6 DISPENSER, OR OTHER INDIVIDUAL.

7 21-2A-07.

8 (A) THE DEPARTMENT AND ITS AGENTS AND EMPLOYEES ARE NOT SUBJECT
9 TO LIABILITY ARISING FROM:

10 (1) THE INACCURACY OF ANY INFORMATION SUBMITTED TO THE
11 PROGRAM IN ACCORDANCE WITH THIS SUBTITLE; AND

12 (2) THE UNAUTHORIZED USE OR DISCLOSURE OF PRESCRIPTION
13 MONITORING DATA PROVIDED TO AN AUTHORIZED RECIPIENT.

14 (B) AN AUTHORIZED RECIPIENT, ACTING IN GOOD FAITH, IS NOT SUBJECT TO
15 LIABILITY ARISING SOLELY FROM FAILURE TO TAKE ACTION ON THE BASIS OF
16 PRESCRIPTION MONITORING DATA PROVIDED BY THE PROGRAM.

17 21-2A-08.

18 (A) THE PROGRAM, IN CONSULTATION WITH THE BOARD, SHALL DEVELOP
19 AND IMPLEMENT, OR CONTRACT WITH A VENDOR TO DEVELOP AND IMPLEMENT,
20 EDUCATION AND TRAINING COURSES RELATING TO THE PROGRAM.

21 (B) THE COURSES REQUIRED UNDER SUBSECTION (A) OF THIS SECTION MAY
22 RELATE TO:

23 (1) THE TRANSMISSION, ACCESS, AND USE OF PRESCRIPTION
24 MONITORING DATA;

25 (2) ISSUES ARISING IN PRESCRIBING AND DISPENSING MONITORED
26 PRESCRIPTION DRUGS; AND

27 (3) ISSUES CONCERNING IDENTIFYING AND TREATING SUBSTANCE
28 ABUSE AND ADDICTION.

29 21-2A-09.

30 (A) A DISPENSER WHO KNOWINGLY FAILS TO SUBMIT PRESCRIPTION
31 MONITORING DATA TO THE PROGRAM AS REQUIRED UNDER THIS SUBTITLE SHALL
32 BE SUBJECT TO A CIVIL PENALTY NOT EXCEEDING \$500 FOR EACH FAILURE TO
33 SUBMIT REQUIRED INFORMATION.

34 (B) AN AUTHORIZED RECIPIENT WHO KNOWINGLY DISCLOSES OR USES
35 PRESCRIPTION MONITORING DATA IN VIOLATION OF THIS SUBTITLE SHALL BE

1 GUILTY OF A MISDEMEANOR AND ON CONVICTION IS SUBJECT TO IMPRISONMENT
2 NOT EXCEEDING 1 YEAR OR A FINE NOT EXCEEDING \$10,000 OR BOTH.

3 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
4 October 1, 2006.