# Chapter 166

(Senate Bill 883)

AN ACT concerning

# **Prescription Drug Monitoring Program**

FOR the purpose of establishing the Prescription Drug Monitoring Program in the Department of Health and Mental Hygiene; establishing the mission of the Program; requiring the Program to carry out its mission by monitoring the prescribing and dispensing of certain substances by certain prescribers and dispensers; establishing the powers and duties of the Department and the Secretary of Health and Mental Hygiene under the Program; requiring dispensers to submit electronically certain information to the Program except in certain circumstances; establishing the Advisory Board on Prescription Drug Monitoring to assist in the design, implementation, and evaluation of the Program; establishing the membership, chair, terms of members, staff support, reimbursement, and responsibilities of the Board; specifying the terms of the initial appointed members of the Board; requiring the Secretary by regulation to establish training protocols and guidelines to assist in the interpretation and evaluation of prescription monitoring data; establishing a technical advisory committee to the Program; establishing the membership and duties of the technical advisory committee; providing that prescription monitoring data are confidential and privileged and not subject to certain means of legal compulsion except under certain circumstances; requiring the Program to disclose prescription monitoring data to certain agencies and persons under certain circumstances; requiring the technical advisory committee to review certain information and provide certain guidance before the Program discloses information to certain agencies and persons; authorizing the Program to disclose prescription monitoring data for certain purposes under certain circumstances; authorizing the Office of the Attorney General to seek certain relief to maintain the confidentiality of prescription monitoring data; authorizing the Program to provide prescription monitoring data to another state's prescription drug monitoring program under certain circumstances; authorizing the Program to request, receive, and use prescription monitoring data from another state's prescription drug monitoring program; authorizing the Program to enter into certain agreements with other states' prescription drug monitoring programs; prohibiting prescription monitoring data from being used as the basis for imposing clinical practice standards; establishing immunity from liability for certain agencies and persons relating to the operation and use of the Program; establishing penalties and disciplinary action for violations of the requirements of the Program; providing that the release of prescription monitoring data in a certain manner is not a violation of the requirements of the Program; providing for the termination of certain provisions

of this Act and certain regulations, subject to the evaluation and reestablishment provisions of the Maryland Program Evaluation Act; requiring a certain evaluation of the Program to be made on or before a certain date; requiring the Program to develop a mechanism to allow certain persons to correct erroneous data reported to the Program; requiring the Department and the Board to report to the Governor and certain committees of the General Assembly on or before a certain date on certain matters relating to the Program; declaring the intent of the General Assembly regarding technology used by the Program; defining certain terms; and generally relating to the establishment and operation of the Prescription Drug Monitoring Program.

# BY renumbering

Article – State Government Section 8–403(b)(54) through (68), respectively to be Section 8–403(b)(55) through (69), respectively Annotated Code of Maryland (2009 Replacement Volume and 2010 Supplement)

# BY adding to

Article – Health – General

Section 21–2A–01 through <del>21–2A–09</del> <u>21–2A–10</u> to be under the new subtitle "Subtitle 2A. Prescription Drug Monitoring Program"

Annotated Code of Maryland

(2009 Replacement Volume and 2010 Supplement)

BY repealing and reenacting, without amendments,

Article – State Government

Section 8–403(a)

Annotated Code of Maryland

(2009 Replacement Volume and 2010 Supplement)

#### BY adding to

Article - State Government

Section 8-403(b)(54)

Annotated Code of Maryland

(2009 Replacement Volume and 2010 Supplement)

# Preamble

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

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

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

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

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

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That Section(s) 8–403(b)(54) through (68), Respectively, of Article – State Government of the Annotated Code of Maryland be renumbered to be Section(s) 8–403(b)(55) through (69), respectively.

SECTION 2. AND BE IT FURTHER ENACTED, That the Laws of Maryland read as follows:

#### Article - Health - General

SUBTITLE 2A. PRESCRIPTION DRUG MONITORING PROGRAM.

#### 21-2A-01.

- (A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS INDICATED.
- (B) "BOARD" MEANS THE ADVISORY BOARD ON PRESCRIPTION DRUG MONITORING.
- (C) (1) "DISPENSE" HAS THE MEANING STATED IN § 12–101 OF THE HEALTH OCCUPATIONS ARTICLE.
  - (2) "DISPENSE" DOES NOT INCLUDE:
- (I) DIRECTLY ADMINISTERING A MONITORED PRESCRIPTION DRUG TO A PATIENT; OR
  - (II) GIVING OUT PRESCRIPTION DRUG SAMPLES.

- (D) (1) "DISPENSER" MEANS A PERSON AUTHORIZED BY LAW TO DISPENSE A MONITORED PRESCRIPTION DRUG TO A PATIENT OR THE PATIENT'S AGENT IN THE STATE.
  - (2) "DISPENSER" INCLUDES A NONRESIDENT PHARMACY.
  - (3) "DISPENSER" DOES NOT INCLUDE:
- (I) A LICENSED HOSPITAL PHARMACY THAT ONLY DISPENSES A MONITORED PRESCRIPTION DRUG FOR DIRECT ADMINISTRATION TO AN INPATIENT OF THE HOSPITAL; AND
  - (II) AN OPIOID MAINTENANCE PROGRAM;
- (III) A VETERINARIAN LICENSED UNDER TITLE 2, SUBTITLE 3 OF THE AGRICULTURE ARTICLE WHEN PRESCRIBING CONTROLLED SUBSTANCES FOR ANIMALS IN THE USUAL COURSE OF PROVIDING PROFESSIONAL SERVICES;
- (IV) A PHARMACY ISSUED A WAIVER PERMIT UNDER COMAR 10.34.17.03 THAT PROVIDES PHARMACEUTICAL SPECIALTY SERVICES EXCLUSIVELY TO PERSONS LIVING IN ASSISTED LIVING FACILITIES, COMPREHENSIVE CARE FACILITIES, AND DEVELOPMENTAL DISABILITIES FACILITIES; AND

#### (V) A PHARMACY THAT:

- 1. <u>Dispenses medications to an inpatient</u> Hospice; and
- 2. HAS BEEN GRANTED A WAIVER UNDER § 21–2A–03(F) OF THIS SUBTITLE.
- (E) "LICENSING ENTITY" MEANS AN ENTITY AUTHORIZED UNDER THE HEALTH OCCUPATIONS ARTICLE TO LICENSE, REGULATE, OR DISCIPLINE A PRESCRIBER OR DISPENSER.
- (F) "MONITORED PRESCRIPTION DRUG" MEANS A PRESCRIPTION DRUG THAT CONTAINS A SCHEDULE II, SCHEDULE III, SCHEDULE IV, OR SCHEDULE V CONTROLLED DANGEROUS SUBSTANCE DESIGNATED UNDER TITLE 5, SUBTITLE 4 OF THE CRIMINAL LAW ARTICLE.
  - (G) "OPIOID MAINTENANCE PROGRAM" MEANS A PROGRAM THAT:

- (1) IS LICENSED BY THE STATE UNDER § 8–404 OF THIS ARTICLE;
- (2) IS AUTHORIZED TO TREAT PATIENTS WITH OPIOID DEPENDENCE WITH A MEDICATION APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION FOR OPIOID DEPENDENCE;
  - (3) COMPLIES WITH:
    - (I) THE CODE OF FEDERAL REGULATIONS 42, PART 8;
    - (II) COMAR 10.47.02.11; AND
- (III) REQUIREMENTS FOR THE SECURE STORAGE AND ACCOUNTING OF OPIOID MEDICATION IMPOSED BY THE FEDERAL DRUG ENFORCEMENT ADMINISTRATION AND THE STATE DIVISION OF DRUG CONTROL; AND
- (4) HAS BEEN GRANTED A CERTIFICATION FOR OPERATION BY THE DEPARTMENT, THE FEDERAL SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION, AND THE FEDERAL CENTER FOR SUBSTANCE ABUSE TREATMENT.
- (G) (H) "PRESCRIBER" MEANS A LICENSED HEALTH CARE PROFESSIONAL AUTHORIZED BY LAW TO PRESCRIBE A MONITORED PRESCRIPTION DRUG.
- (H) (I) "Prescription drug" has the meaning stated in § 21–201 of this title.
- (1) (J) "PRESCRIPTION MONITORING DATA" MEANS THE INFORMATION SUBMITTED TO THE PROGRAM FOR A MONITORED PRESCRIPTION DRUG.
- (J) (K) "Program" means the Prescription Drug Monitoring Program established under this subtitle.
- 21-2A-02.
- (A) THERE IS A PRESCRIPTION DRUG MONITORING PROGRAM IN THE DEPARTMENT.
  - (B) THE MISSION OF THE PROGRAM IS TO:

- (1) ASSIST PRESCRIBERS, DISPENSERS, AND PUBLIC HEALTH PROFESSIONALS IN:
- (I) THE IDENTIFICATION<del>, TREATMENT,</del> AND PREVENTION OF PRESCRIPTION DRUG ABUSE; AND
- (II) THE IDENTIFICATION AND INVESTIGATION OF UNLAWFUL PRESCRIPTION DRUG DIVERSION; AND
- (2) PROMOTE A BALANCED USE OF PRESCRIPTION MONITORING DATA TO ASSIST APPROPRIATE LAW ENFORCEMENT ACTIVITIES WHILE PRESERVING THE PROFESSIONAL PRACTICE OF HEALTH CARE PROVIDERS AND THE ACCESS OF PATIENTS TO OPTIMAL PHARMACEUTICAL CARE.
- (C) TO CARRY OUT ITS MISSION, THE PROGRAM SHALL MONITOR THE PRESCRIBING AND DISPENSING OF ALL SCHEDULE II, SCHEDULE III, SCHEDULE IV, AND SCHEDULE V CONTROLLED DANGEROUS SUBSTANCES BY ALL PRESCRIBERS AND DISPENSERS IN THE STATE.

#### 21-2A-03.

(A) THE DEPARTMENT SHALL IMPLEMENT THE PROGRAM, SUBJECT TO THE AVAILABILITY OF FUNDS.

#### (B) THE SECRETARY MAY:

- (1) ASSIGN RESPONSIBILITY FOR THE OPERATION OF THE PROGRAM TO ANY UNIT IN THE DEPARTMENT; AND
- (2) CONTRACT WITH ANY QUALIFIED PERSON FOR THE EFFICIENT AND ECONOMICAL OPERATION OF THE PROGRAM.
- (C) EXCEPT AS PROVIDED IN SUBSECTION (D) OF THIS SECTION, EACH DISPENSER SHALL SUBMIT PRESCRIPTION MONITORING DATA TO THE PROGRAM BY ELECTRONIC MEANS, IN ACCORDANCE WITH REGULATIONS ADOPTED BY THE SECRETARY.
- (D) THE SECRETARY, FOR GOOD CAUSE SHOWN, MAY AUTHORIZE A DISPENSER TO SUBMIT PRESCRIPTION MONITORING DATA BY AN ALTERNATIVE FORM OF SUBMISSION.
- (E) THE SECRETARY, IN CONSULTATION WITH THE MARYLAND HEALTH CARE COMMISSION AND THE BOARD, SHALL:

- (1) ESTABLISH A WEB SITE FOR THE PROGRAM DETERMINE THE APPROPRIATE TECHNOLOGY TO SUPPORT THE OPERATION OF THE PROGRAM; AND
- (2) EDUCATE DISPENSERS, PRESCRIBERS, AND CONSUMERS ABOUT THE PURPOSE AND OPERATION OF THE PROGRAM.
- (F) (1) THE SECRETARY SHALL GRANT A WAIVER TO A PHARMACY THAT DISPENSES MEDICATIONS TO AN INPATIENT HOSPICE FROM REPORTING TO THE PROGRAM PRESCRIPTION MONITORING DATA FOR HOSPICE INPATIENTS IF:
- (I) THE PHARMACY DEMONSTRATES HOW IT WILL DISTINGUISH HOSPICE INPATIENTS FROM OTHER CONSUMERS RECEIVING MEDICATIONS FROM THE PHARMACY; AND
- (II) THE PHARMACY AGREES THAT IT WILL BE SUBJECT TO ONSITE, UNANNOUNCED INSPECTIONS BY THE DEPARTMENT TO VERIFY ITS REPORTING OF THE PRESCRIPTION DATA OF CONSUMERS WHO ARE NOT HOSPICE INPATIENTS.
- (2) A WAIVER GRANTED UNDER THIS SUBSECTION MAY REMAIN IN EFFECT FOR UP TO 2 YEARS.
- (3) THE SECRETARY MAY ESTABLISH AN APPLICATION PROCESS FOR A PHARMACY TO APPLY FOR A WAIVER UNDER THIS SUBSECTION.

  21–2A–04.
- (A) THE SECRETARY, IN CONSULTATION WITH THE BOARD, SHALL ADOPT REGULATIONS TO CARRY OUT THIS SUBTITLE.
  - (B) THE REGULATIONS ADOPTED BY THE SECRETARY SHALL:
- (1) SPECIFY THE PRESCRIPTION MONITORING DATA REQUIRED TO BE SUBMITTED UNDER § 21–2A–03 OF THIS SUBTITLE;
- (2) SPECIFY THE ELECTRONIC OR OTHER MEANS BY WHICH INFORMATION IS TO BE SUBMITTED:
- (I) WITHOUT UNDULY INCREASING THE WORKLOAD AND EXPENSE ON DISPENSERS AND PRESCRIBERS; AND

(II) IN A MANNER AS COMPATIBLE AS POSSIBLE WITH EXISTING DATA SUBMISSION PRACTICES OF DISPENSERS;

# (3) SPECIFY THAT THE PROGRAM:

- (I) SHALL PROVIDE THE INFORMATION TECHNOLOGY SOFTWARE TO DISPENSERS NECESSARY TO UPLOAD PRESCRIPTION DRUG MONITORING DATA TO THE PROGRAM; AND
- (II) MAY NOT IMPOSE ANY FEES OR OTHER ASSESSMENTS
  ON PRESCRIBERS OR DISPENSERS TO SUPPORT THE OPERATION OF THE
  PROGRAM;
- (3) (4) SPECIFY THAT A PRESCRIBER OR DISPENSER IS NOT REQUIRED OR OBLIGATED TO ACCESS OR USE PRESCRIPTION MONITORING DATA AVAILABLE UNDER THE PROGRAM;
- (4) (5) IDENTIFY THE MECHANISM BY WHICH PRESCRIPTION MONITORING DATA ARE DISCLOSED TO A PERSON, IN ACCORDANCE WITH § 21–2A–07 OF THIS SUBTITLE;
- (5) (6) IDENTIFY THE CIRCUMSTANCES UNDER WHICH A PERSON MAY DISCLOSE PRESCRIPTION MONITORING DATA RECEIVED UNDER THE PROGRAM;
- (6) ESTABLISH TRAINING PROTOCOLS AND GUIDELINES TO ASSIST LAW ENFORCEMENT AGENCIES AND LICENSING ENTITIES IN THE APPROPRIATE INTERPRETATION AND EVALUATION OF PRESCRIPTION MONITORING DATA IN THE CONTEXT OF THE NATURE OF:
  - (I) A PRESCRIBER'S OR DISPENSER'S PRACTICE;
  - (H) A PATIENT'S MEDICAL CONDITION; OR
  - (III) ANY OTHER RELEVANT FACTS;
- (7) ESTABLISH REQUIREMENTS FOR PROGRAM RETENTION OF PRESCRIPTION MONITORING DATA FOR 3 YEARS; AND
  - (8) REQUIRE THAT:
- (I) CONFIDENTIAL OR PRIVILEGED PATIENT INFORMATION BE KEPT CONFIDENTIAL; AND

(II) RECORDS OR INFORMATION PROTECTED BY A PRIVILEGE BETWEEN A HEALTH CARE PROVIDER AND A PATIENT, OR OTHERWISE REQUIRED BY LAW TO BE HELD CONFIDENTIAL, BE FILED IN A MANNER THAT, EXCEPT AS OTHERWISE PROVIDED IN \$21-2A-07 \ 21-2A-06 OF THIS SUBTITLE, DOES NOT DISCLOSE THE IDENTITY OF THE PERSON PROTECTED.

#### 21-2A-05.

- (A) THERE IS AN ADVISORY BOARD ON PRESCRIPTION DRUG MONITORING IN THE DEPARTMENT.
- (B) THE SECRETARY SHALL APPOINT MEMBERS TO THE BOARD, INCLUDING MEMBERS REPRESENTING THE PERSPECTIVE OF:
  - (1) PRESCRIBERS:
  - (2) DISPENSERS:
  - (3) LICENSING ENTITIES;
- (4) HEALTH CARE PRACTITIONERS WITH EXPERTISE IN THE AREAS OF PAIN MANAGEMENT, SUBSTANCE ABUSE TREATMENT, AND ADDICTION TREATMENT:
  - (5) LAW ENFORCEMENT:
  - (6) PAIN PATIENTS: AND
- (7) ANY OTHER INDIVIDUAL OR REPRESENTATIVE AT THE SECRETARY'S DISCRETION.
  - (C) THE SECRETARY SHALL:
    - (1) DESIGNATE THE CHAIR OF THE BOARD;
- (2) DETERMINE THE NUMBER OF BOARD MEMBERS AND ENSURE BALANCED REPRESENTATION ON THE BOARD OF THE GROUPS DESCRIBED IN SUBSECTION (B) OF THIS SECTION:
  - (3) DETERMINE THE TERMS OF BOARD MEMBERS:
  - (4) FILL VACANCIES ON THE BOARD; AND

- (5) Provide Staff Support for the Board.
- (B) THE BOARD SHALL CONSIST OF THE FOLLOWING MEMBERS:
  - (1) THE SECRETARY, OR THE SECRETARY'S DESIGNEE;
- (2) THE PRESIDENT OF THE MARYLAND BOARD OF PHARMACY, OR THE PRESIDENT'S DESIGNEE;
- (3) THE CHAIR OF THE MARYLAND BOARD OF PHYSICIANS, OR THE CHAIR'S DESIGNEE;
- (4) THE PRESIDENT OF THE MARYLAND BOARD OF NURSING, OR THE PRESIDENT'S DESIGNEE;
- (5) THE CHAIRMAN OF THE MARYLAND HEALTH CARE COMMISSION, OR THE CHAIRMAN'S DESIGNEE;
- (6) FOUR PHYSICIANS AND ONE NURSE PRACTITIONER WITH EXPERTISE IN CLINICAL TREATMENT USING CONTROLLED DANGEROUS SUBSTANCES, INCLUDING PAIN MANAGEMENT, SUBSTANCE ABUSE, AND BEHAVIORAL DISORDERS, APPOINTED BY THE SECRETARY AFTER CONSULTATION WITH:
- AND CHIRURGICAL FACULTY OF MARYLAND, THE MARYLAND PHYSICAL MEDICINE AND REHABILITATION SOCIETY, THE MARYLAND SOCIETY OF ANESTHESIOLOGISTS, THE MARYLAND-D.C. SOCIETY OF CLINICAL ONCOLOGY, THE HOSPICE AND PALLIATIVE CARE NETWORK OF MARYLAND, AND THE MARYLAND CHAPTER OF THE AMERICAN ACADEMY OF PEDIATRICS; AND
- (II) FOR THE NURSE PRACTITIONER APPOINTMENT, THE MARYLAND NURSES ASSOCIATION;
- (7) ONE PEDIATRICIAN, APPOINTED BY THE SECRETARY AFTER CONSULTATION WITH THE MARYLAND CHAPTER OF THE AMERICAN ACADEMY OF PEDIATRICS;
- (8) THREE PHARMACISTS WHO REPRESENT THE PERSPECTIVE OF INDEPENDENT AND CHAIN PHARMACIES, APPOINTED BY THE SECRETARY AFTER CONSULTATION WITH THE MARYLAND PHARMACISTS ASSOCIATION, THE

# MARYLAND ASSOCIATION OF CHAIN DRUG STORES, AND ANY OTHER APPROPRIATE ORGANIZATION;

- (9) A LOCAL LAW ENFORCEMENT OFFICIAL, APPOINTED BY THE SECRETARY AFTER CONSULTATION WITH THE MARYLAND CHIEFS OF POLICE ASSOCIATION AND THE MARYLAND SHERIFF'S ASSOCIATION;
- (10) TWO MARYLAND RESIDENTS WHO REPRESENT THE PERSPECTIVE OF PATIENTS, APPOINTED BY THE SECRETARY.
  - (C) THE SECRETARY SHALL DESIGNATE THE CHAIR OF THE BOARD.
- (D) (1) THE TERM OF A MEMBER APPOINTED BY THE SECRETARY IS 3 YEARS.
- (2) THE TERMS OF MEMBERS APPOINTED BY THE SECRETARY ARE STAGGERED AS REQUIRED BY THE TERMS PROVIDED FOR MEMBERS OF THE BOARD ON OCTOBER 1, 2011.
- (3) IF A VACANCY OCCURS DURING THE TERM OF AN APPOINTED MEMBER, THE SECRETARY SHALL APPOINT A SUCCESSOR WHO SHALL SERVE UNTIL THE TERM EXPIRES.
  - (D) (E) A MEMBER OF THE BOARD:
- (1) MAY NOT RECEIVE COMPENSATION AS A MEMBER OF THE BOARD; BUT
- (2) IS ENTITLED TO REIMBURSEMENT FOR EXPENSES UNDER THE STANDARD STATE TRAVEL REGULATIONS, AS PROVIDED IN THE STATE BUDGET.
  - (E) (F) THE BOARD SHALL:
    - (1) MEET NOT FEWER THAN THREE TIMES ANNUALLY;
- (2) MAKE RECOMMENDATIONS TO THE SECRETARY RELATING TO THE DESIGN AND IMPLEMENTATION OF THE PROGRAM, INCLUDING RECOMMENDATIONS RELATING TO:
  - (I) REGULATIONS;
  - (II) LEGISLATION; AND

- (III) SOURCES OF FUNDING, INCLUDING GRANT FUNDS UNDER THE HAROLD ROGERS PRESCRIPTION DRUG MONITORING PROGRAM AND OTHER SOURCES OF FEDERAL, PRIVATE, OR STATE FUNDS;
- (3) (I) PROVIDE WITHIN 180 DAYS AFTER ITS FIRST MEETING, IN ACCORDANCE WITH § 2–1246 OF THE STATE GOVERNMENT ARTICLE, AN INTERIM REPORT TO THE GENERAL ASSEMBLY SETTING FORTH THE BOARD'S ANALYSIS AND RECOMMENDATIONS UNDER ITEM (2) OF THIS SUBSECTION RELATING TO THE DESIGN, IMPLEMENTATION, AND FUNDING OF THE PROGRAM; AND
- (II) PROVIDE ANNUALLY TO THE GOVERNOR AND, IN ACCORDANCE WITH § 2–1246 OF THE STATE GOVERNMENT ARTICLE, THE GENERAL ASSEMBLY AN ANALYSIS OF THE IMPACT OF THE PROGRAM ON PATIENT ACCESS TO PHARMACEUTICAL CARE AND ON CURBING PRESCRIPTION DRUG DIVERSION IN THE STATE, INCLUDING ANY RECOMMENDATIONS RELATED TO MODIFICATION OR CONTINUATION OF THE PROGRAM; AND
- (4) PROVIDE ONGOING ADVICE AND CONSULTATION ON THE IMPLEMENTATION AND OPERATION OF THE PROGRAM, INCLUDING RECOMMENDATIONS RELATING TO:
- (I) CHANGES IN THE PROGRAM TO REFLECT ADVANCES IN TECHNOLOGY AND BEST PRACTICES IN THE FIELD OF ELECTRONIC HEALTH RECORDS AND ELECTRONIC PRESCRIPTION MONITORING;
  - (II) CHANGES TO STATUTORY REQUIREMENTS; AND
- (III) THE DESIGN AND IMPLEMENTATION OF AN ONGOING EVALUATION COMPONENT OF THE PROGRAM.
- (G) THE SECRETARY AND THE BOARD SHALL CONSULT WITH STAKEHOLDERS AND PROFESSIONALS KNOWLEDGEABLE ABOUT PRESCRIPTION DRUG MONITORING PROGRAMS AS APPROPRIATE TO OBTAIN INPUT AND GUIDANCE ABOUT IMPLEMENTATION OF THE PROGRAM.

#### 21-2A-06.

#### (A) PRESCRIPTION MONITORING DATA:

(1) ARE CONFIDENTIAL AND PRIVILEGED, AND NOT SUBJECT TO DISCOVERY, SUBPOENA, OR OTHER MEANS OF LEGAL COMPULSION IN CIVIL LITIGATION;

- (2) ARE NOT PUBLIC RECORDS; AND
- (3) EXCEPT AS PROVIDED IN SUBSECTIONS (B) AND (D) OF THIS SECTION OR AS OTHERWISE PROVIDED BY LAW, MAY NOT BE DISCLOSED TO ANY PERSON.
- (B) THE PROGRAM SHALL DISCLOSE PRESCRIPTION MONITORING DATA, IN ACCORDANCE WITH REGULATIONS <u>ADOPTED BY THE SECR</u>ETARY, TO:
- (1) A PRESCRIBER, OR <del>ANY OTHER PERSON</del> <u>A LICENSED HEALTH</u> <u>CARE PRACTITIONER</u> AUTHORIZED BY THE PRESCRIBER, IN CONNECTION WITH THE MEDICAL CARE OF A PATIENT;
- (2) A DISPENSER, OR <del>ANY OTHER PERSON</del> <u>A LICENSED HEALTH</u> <u>CARE PRACTITIONER</u> AUTHORIZED BY THE DISPENSER, IN CONNECTION WITH THE DISPENSING OF A MONITORED PRESCRIPTION DRUG;
- (3) A FEDERAL LAW ENFORCEMENT AGENCY OR A STATE OR LOCAL LAW ENFORCEMENT AGENCY, ON ISSUANCE OF A SUBPOENA, FOR THE PURPOSE OF FURTHERING AN EXISTING BONA FIDE INDIVIDUAL INVESTIGATION;
- (4) A LICENSING ENTITY, ON ISSUANCE OF AN ADMINISTRATIVE SUBPOENA VOTED ON BY A QUORUM OF THE BOARD OF THE LICENSING ENTITY, FOR THE PURPOSES OF FURTHERING AN EXISTING BONA FIDE INDIVIDUAL INVESTIGATION;
- (5) A REHABILITATION PROGRAM UNDER A HEALTH OCCUPATIONS BOARD, ON ISSUANCE OF AN ADMINISTRATIVE SUBPOENA;
- (5) (6) A PATIENT WITH RESPECT TO PRESCRIPTION MONITORING DATA ABOUT THE PATIENT;
- $\frac{(6)}{(7)}$  AN SUBJECT TO SUBSECTION (G) OF THIS SECTION, THE AUTHORIZED ADMINISTRATOR OF ANOTHER STATE'S PRESCRIPTION DRUG MONITORING PROGRAM;  $\frac{OR}{OR}$
- (7) (8) A UNIT THE FOLLOWING UNITS OF THE DEPARTMENT, ON APPROVAL OF THE SECRETARY, FOR THE PURPOSE OF FURTHERING AN EXISTING BONA FIDE INDIVIDUAL INVESTIGATION:
  - (I) THE OFFICE OF THE CHIEF MEDICAL EXAMINER;

- (II) THE MARYLAND MEDICAL ASSISTANCE PROGRAM;
- (III) THE OFFICE OF THE INSPECTOR GENERAL; AND
- (IV) THE OFFICE OF HEALTH CARE QUALITY; OR
- (9) THE TECHNICAL ADVISORY COMMITTEE ESTABLISHED UNDER § 21–2A–07 OF THIS SUBTITLE FOR THE PURPOSES SET FORTH IN SUBSECTION (C) OF THIS SECTION.
- (C) BEFORE THE PROGRAM DISCLOSES INFORMATION UNDER SUBSECTION (B)(3), (4), (5), (7), OR (8) OF THIS SECTION, THE TECHNICAL ADVISORY COMMITTEE TO THE PROGRAM SHALL:
  - (1) REVIEW THE REQUESTS FOR INFORMATION;
- (2) PROVIDE CLINICAL GUIDANCE AND INTERPRETATION OF THE INFORMATION REQUESTED TO THE SECRETARY TO ASSIST IN THE SECRETARY'S DECISION ON HOW TO RESPOND TO A JUDICIAL SUBPOENA, ADMINISTRATIVE SUBPOENA, OR OTHER REQUEST; AND
- (3) PROVIDE CLINICAL GUIDANCE AND INTERPRETATION OF THE INFORMATION REQUESTED TO THE AUTHORIZED RECIPIENT OF THE INFORMATION.
- (C) (D) EXCEPT AS PROVIDED BY REGULATIONS ADOPTED BY THE SECRETARY, A PERSON WHO RECEIVES PRESCRIPTION MONITORING DATA FROM THE PROGRAM MAY NOT DISCLOSE THE DATA.
- (D) (E) (1) IN ADDITION TO THE DISCLOSURES REQUIRED UNDER SUBSECTION (B) OF THIS SECTION, THE PROGRAM MAY DISCLOSE PRESCRIPTION MONITORING DATA FOR RESEARCH, ANALYSIS, PUBLIC REPORTING, AND EDUCATION:
- (I) AFTER REDACTION OF ALL INFORMATION THAT COULD IDENTIFY A PATIENT, PRESCRIBER, DISPENSER, OR ANY OTHER INDIVIDUAL; AND
- (II) IN ACCORDANCE WITH REGULATIONS ADOPTED BY THE SECRETARY.
- (2) THE SECRETARY MAY REQUIRE SUBMISSION OF AN ABSTRACT EXPLAINING THE SCOPE AND PURPOSE OF THE RESEARCH, ANALYSIS, PUBLIC

REPORTING, OR EDUCATION BEFORE DISCLOSING PRESCRIPTION MONITORING DATA UNDER THIS SUBSECTION.

(E) (F) THE OFFICE OF THE ATTORNEY GENERAL MAY SEEK APPROPRIATE INJUNCTIVE OR OTHER RELIEF TO MAINTAIN THE CONFIDENTIALITY OF PRESCRIPTION MONITORING DATA AS REQUIRED UNDER THIS SECTION.

# (F) (G) THE PROGRAM MAY:

(1) PROVIDE PROVIDE PRESCRIPTION MONITORING DATA TO ANOTHER STATE'S PRESCRIPTION DRUG MONITORING PROGRAM, PROVIDED ONLY IF THE OTHER STATE'S PRESCRIPTION DRUG MONITORING PROGRAM AGREES TO USE THE PRESCRIPTION MONITORING DATA IN A MANNER CONSISTENT WITH THE PROVISIONS OF THIS SUBTITLE.

# (H) THE PROGRAM MAY:

- (2) (1) REQUEST AND RECEIVE PRESCRIPTION MONITORING DATA FROM ANOTHER STATE'S PRESCRIPTION DRUG MONITORING PROGRAM AND USE THE PRESCRIPTION MONITORING DATA IN A MANNER CONSISTENT WITH THE PROVISIONS OF THIS SUBTITLE; AND
- (3) (2) DEVELOP THE CAPABILITY TO TRANSMIT PRESCRIPTION MONITORING DATA TO AND RECEIVE PRESCRIPTION MONITORING DATA FROM OTHER PRESCRIPTION DRUG MONITORING PROGRAMS EMPLOYING THE STANDARDS OF INTEROPERABILITY.
- (G) (I) THE PROGRAM MAY ENTER INTO WRITTEN AGREEMENTS WITH OTHER STATES' PRESCRIPTION DRUG MONITORING PROGRAMS FOR THE PURPOSE OF ESTABLISHING THE TERMS AND CONDITIONS FOR SHARING PRESCRIPTION MONITORING DATA UNDER THIS SECTION.
- (J) PRESCRIPTION MONITORING DATA MAY NOT BE USED AS THE BASIS FOR IMPOSING CLINICAL PRACTICE STANDARDS.

#### 21-2A-07.

- (A) THERE IS A TECHNICAL ADVISORY COMMITTEE TO THE PROGRAM.
- (B) THE PURPOSE OF THE TECHNICAL ADVISORY COMMITTEE IS TO REVIEW REQUESTS FOR INFORMATION FROM THE PROGRAM UNDER § 21–2A–06(B)(3), (4), (5), (7), AND (8) OF THIS SUBTITLE.

- (C) THE TECHNICAL ADVISORY COMMITTEE CONSISTS OF THE FOLLOWING MEMBERS, APPOINTED BY THE SECRETARY:
- (1) A BOARD CERTIFIED ANESTHESIOLOGIST LICENSED AND PRACTICING IN THE STATE, NOMINATED BY THE MARYLAND SOCIETY OF ANESTHESIOLOGISTS;
- (2) A CERTIFIED ADDICTION MEDICINE SPECIALIST LICENSED AND PRACTICING IN THE STATE, NOMINATED BY THE MARYLAND SOCIETY FOR ADDICTION MEDICINE;
  - (3) A PHARMACIST LICENSED AND PRACTICING IN THE STATE:
- (4) A MEDICAL PROFESSIONAL, LICENSED AND PRACTICING IN THE STATE, WHO IS TREATING CANCER PATIENTS; AND
- (5) A BOARD CERTIFIED PHYSICIAN SPECIALIZING IN THE TREATMENT OF PATIENTS WITH PAIN, LICENSED AND PRACTICING IN THE STATE, NOMINATED BY THE MARYLAND SOCIETY OF PHYSICAL MEDICINE AND REHABILITATION.

# 21-2A-08.

- (A) THE WITH RESPECT TO THE ADMINISTRATION AND OPERATION OF THE PROGRAM, THE DEPARTMENT AND ITS AGENTS AND EMPLOYEES ARE NOT SUBJECT TO LIABILITY ARISING FROM:
- (1) THE INACCURACY OF ANY INFORMATION SUBMITTED TO THE PROGRAM IN ACCORDANCE WITH THIS SUBTITLE; OR
- (2) THE UNAUTHORIZED USE OR DISCLOSURE OF PRESCRIPTION MONITORING DATA PROVIDED TO BY A PERSON TO WHOM THE PROGRAM WAS AUTHORIZED TO PROVIDE THE PRESCRIPTION MONITORING DATA UNDER THIS SUBTITLE.
- (B) A PRESCRIBER OR DISPENSER, ACTING IN GOOD FAITH, IS NOT SUBJECT TO LIABILITY OR DISCIPLINARY ACTION ARISING SOLELY FROM:
- (1) REQUESTING OR RECEIVING, OR FAILING TO REQUEST OR RECEIVE, PRESCRIPTION MONITORING DATA FROM THE PROGRAM; OR
- (2) ACTING, OR FAILING TO ACT, ON THE BASIS OF PRESCRIPTION MONITORING DATA PROVIDED BY THE PROGRAM.

#### <del>21-2A-08.</del> 21-2A-09.

- (A) A DISPENSER WHO KNOWINGLY FAILS TO SUBMIT PRESCRIPTION MONITORING DATA TO THE PROGRAM AS REQUIRED UNDER THIS SUBTITLE SHALL BE SUBJECT TO A CIVIL PENALTY NOT EXCEEDING \$500 FOR EACH FAILURE TO SUBMIT REQUIRED INFORMATION.
- (B) A PRESCRIBER OR DISPENSER WHO KNOWINGLY VIOLATES ANY PROVISION OF THIS SUBTITLE IS LIABLE FOR:
  - (1) ACTUAL DAMAGES; AND
  - (2) REASONABLE ATTORNEY'S FEES.
- (C) (B) (1) A PERSON WHO KNOWINGLY DISCLOSES OR USES DISCLOSES, USES, OBTAINS, OR ATTEMPTS TO OBTAIN BY FRAUD OR DECEIT, PRESCRIPTION MONITORING DATA IN VIOLATION OF THIS SUBTITLE SHALL BE GUILTY OF A MISDEMEANOR AND ON CONVICTION IS SUBJECT TO IMPRISONMENT NOT EXCEEDING 1 YEAR OR A FINE NOT EXCEEDING \$10,000 OR BOTH.
- (2) IN ADDITION TO THE PENALTIES UNDER PARAGRAPH (1) OF THIS SUBSECTION, A PRESCRIBER OR DISPENSER WHO KNOWINGLY DISCLOSES OR USES PRESCRIPTION MONITORING DATA IN VIOLATION OF THIS SUBTITLE SHALL BE SUBJECT TO DISCIPLINARY ACTION BY THE APPROPRIATE LICENSING ENTITY.
- (3) THE RELEASE OF PRESCRIPTION MONITORING DATA BY A PRESCRIBER OR DISPENSER TO A LICENSED HEALTH CARE PROFESSIONAL SOLELY FOR TREATMENT PURPOSES IN A MANNER OTHERWISE CONSISTENT WITH STATE AND FEDERAL LAW IS NOT A VIOLATION OF THIS SUBTITLE.

# <del>21-2A-09.</del> 21-2A-10.

SUBJECT TO THE EVALUATION AND REESTABLISHMENT PROVISIONS OF THE MARYLAND PROGRAM EVALUATION ACT, THIS SUBTITLE AND ALL REGULATIONS ADOPTED UNDER THIS SUBTITLE SHALL TERMINATE AND BE OF NO EFFECT AFTER JULY 1, 2016.

#### Article - State Government

8-403.

- (a) On or before December 15 of the 2nd year before the evaluation date of a governmental activity or unit, the Legislative Policy Committee, based on a preliminary evaluation, may waive as unnecessary the evaluation required under this section.
- (b) Except as otherwise provided in subsection (a) of this section, on or before the evaluation date for the following governmental activities or units, an evaluation shall be made of the following governmental activities or units and the statutes and regulations that relate to the governmental activities or units:
- (54) PRESCRIPTION DRUG MONITORING PROGRAM IN THE DEPARTMENT OF HEALTH AND MENTAL HYGIENE (§ 21–2A–02 OF THE HEALTH GENERAL ARTICLE: JULY 1, 2015);

SECTION 3. AND BE IT FURTHER ENACTED, That the terms of the initial appointed members of the Advisory Board on Prescription Drug Monitoring established under Section 2 of this Act shall expire as follows:

- (1) four members in 2013;
- (2) four members in 2014; and
- (3) three members in 2015.

SECTION 4. AND BE IT FURTHER ENACTED, That the Prescription Drug Monitoring Program established under Section 2 of this Act shall develop a mechanism to allow a patient or the patient's prescriber to correct erroneous data reported to the Program relating to the patient's prescription history.

SECTION 5. AND BE IT FURTHER ENACTED, That, on or before December 1, 2012, the Department and the Advisory Board on Prescription Drug Monitoring established under Section 2 of this Act shall report to the Governor and, in accordance with § 2–1246 of the State Government Article, the Senate Finance Committee and the House Health and Government Operations Committee on:

- (1) the status and funding of the Prescription Drug Monitoring Program established under Section 2 of this Act;
  - (2) <u>feedback from stakeholders on the operations of the Program;</u>
- (3) any recommendations from the Department and the Advisory Board to improve the operations of the Program; and
- (4) whether a legislative safe harbor provision is recommended to address any access issues experienced by patients after implementation of the Program.

SECTION 6. AND BE IT FURTHER ENACTED, That it is the intent of the General Assembly that the Secretary of Health and Mental Hygiene, in adopting regulations for the Prescription Drug Monitoring Program established under Section 2 of this Act, shall ensure that the technology used by the Program to report prescription monitoring data to authorized recipients is not subject to manipulation by the recipient.

SECTION  $\frac{1}{2}$  AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2011.

Approved by the Governor, May 10, 2011.