

SENATE BILL 537

J1, J2

6lr3249
CF HB 437

By: **Senator Klausmeier**

Introduced and read first time: February 4, 2016

Assigned to: Finance

A BILL ENTITLED

1 AN ACT concerning

2 **Department of Health and Mental Hygiene – Prescription Drug Monitoring**
3 **Program – Modifications**

4 FOR the purpose of requiring that certain authorized providers and prescribers be
5 registered with the Prescription Drug Monitoring Program before obtaining a certain
6 new or renewal registration or by a certain date, whichever is sooner; requiring that
7 certain pharmacists be registered with the Program by a certain date; requiring a
8 prescriber and a pharmacist to complete a certain course of instruction before
9 registering with the Program; altering the mission of the Program; authorizing the
10 Secretary of Health and Mental Hygiene to identify and publish a list of certain
11 monitored prescription drugs; requiring the Secretary, in consultation with the
12 Maryland Health Care Commission and the Advisory Board on Prescription Drug
13 Monitoring, to educate pharmacists, prescriber delegates, and pharmacist delegates
14 about the purpose and operation of the Program; altering a requirement that certain
15 regulations adopted by the Secretary specify that a prescriber or dispenser is not
16 required or obligated to access or use certain prescription monitoring data to instead
17 require the regulations to specify the circumstances under which a prescriber or a
18 pharmacist is required to request prescription monitoring data from the Program;
19 requiring that certain regulations adopted by the Secretary specify a process for the
20 Program's review of prescription monitoring data and reporting of a possible
21 violation of law or breach of professional standards; requiring certain prescribers
22 and pharmacists to request and assess certain prescription monitoring data under
23 certain circumstances; requiring a certain prescriber to document certain
24 information in a patient's medical records under certain circumstances; authorizing
25 a certain prescriber or pharmacist to authorize a prescriber delegate or pharmacist
26 delegate to request prescription monitoring data on behalf of the prescriber or
27 pharmacist under certain circumstances; specifying the circumstances under which
28 certain prescribers and pharmacists are not required to request prescription
29 monitoring data from the Program or to comply with certain provisions of this Act;
30 requiring certain prescribers and pharmacists who do not access prescription
31 monitoring data to take certain actions; requiring, instead of authorizing, the

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 Program to review prescription monitoring data for signs of certain misuse or abuse
2 and requiring, instead of authorizing, the Program to report the possible misuse or
3 abuse to a certain prescriber or pharmacist; requiring the Program to review
4 prescription monitoring data for indications of a possible violation of law or a breach
5 of professional standards by a prescriber or a pharmacist; requiring the Program to
6 provide certain notification and information under certain circumstances; altering
7 the information that the Advisory Board on Prescription Drug Monitoring must
8 report annually to the Governor and the General Assembly; altering a certain
9 immunity from liability or disciplinary action arising solely from certain actions;
10 providing that prescribers, prescriber delegates, pharmacists, and pharmacist
11 delegates shall be subject to disciplinary action by the appropriate licensing entity
12 for certain violations; providing that a release of prescription monitoring data by a
13 prescriber delegate, pharmacist, or pharmacist delegate under certain circumstances
14 is not a violation of certain provisions of law; altering certain definitions; defining
15 certain terms; making certain technical corrections; and generally relating to the
16 Prescription Drug Monitoring Program.

17 BY repealing and reenacting, with amendments,
18 Article – Criminal Law
19 Section 5–304
20 Annotated Code of Maryland
21 (2012 Replacement Volume and 2015 Supplement)

22 BY repealing and reenacting, without amendments,
23 Article – Health – General
24 Section 21–2A–01(a), (e), and (f), 21–2A–02(c), and 21–2A–03(a)
25 Annotated Code of Maryland
26 (2015 Replacement Volume)

27 BY repealing and reenacting, with amendments,
28 Article – Health – General
29 Section 21–2A–01(d), (g), (h), (i), (j), and (k), 21–2A–02(b), 21–2A–03(b) and (e),
30 21–2A–04, 21–2A–05(f)(3)(i) and (ii), 21–2A–06, 21–2A–07(b), 21–2A–08(b),
31 and 21–2A–09
32 Annotated Code of Maryland
33 (2015 Replacement Volume)

34 BY adding to
35 Article – Health – General
36 Section 21–2A–01(h), (i), (k), (o), and (p), 21–2A–04.1, and 21–2A–04.2
37 Annotated Code of Maryland
38 (2015 Replacement Volume)

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

41 **Article – Criminal Law**

1 5-304.

2 (a) If an authorized provider is authorized to dispense or conduct research under
3 State law, the Department shall register the authorized provider to dispense a controlled
4 dangerous substance or to conduct research with a controlled dangerous substance listed
5 in Schedule II through Schedule V.

6 **(B) AN AUTHORIZED PROVIDER WHO PRESCRIBES A CONTROLLED**
7 **DANGEROUS SUBSTANCE LISTED IN SCHEDULE II THROUGH SCHEDULE V SHALL BE**
8 **REGISTERED WITH THE PRESCRIPTION DRUG MONITORING PROGRAM DESCRIBED**
9 **IN TITLE 21, SUBTITLE 2A OF THE HEALTH – GENERAL ARTICLE BEFORE**
10 **OBTAINING A NEW OR RENEWAL REGISTRATION WITH THE DEPARTMENT UNDER**
11 **SUBSECTION (A) OF THIS SECTION OR BY JULY 1, 2017, WHICHEVER IS SOONER.**

12 **[(b)] (C)** The Department need not require separate registration under this
13 section for an authorized provider who is:

14 (1) engaged in research with a nonnarcotic controlled dangerous substance
15 in Schedule II through Schedule V; and

16 (2) already registered under this subtitle in another capacity.

17 **[(c)] (D)** An authorized provider may conduct research in the State with a
18 controlled dangerous substance listed in Schedule I if the authorized provider is registered
19 under federal law to conduct research with a controlled dangerous substance listed in
20 Schedule I and gives evidence of the registration to the Department.

21 **Article – Health – General**

22 21-2A-01.

23 (a) In this subtitle the following words have the meanings indicated.

24 (d) (1) “Dispenser” means a person authorized by law to dispense a monitored
25 prescription drug to a patient or the patient’s agent in the State.

26 (2) “Dispenser” includes a nonresident pharmacy.

27 (3) “Dispenser” does not include:

28 (i) A licensed hospital pharmacy that only dispenses a monitored
29 prescription drug for direct administration to an inpatient of the hospital;

30 (ii) An opioid **[maintenance]** **TREATMENT SERVICES** program;

1 (iii) A veterinarian licensed under Title 2, Subtitle 3 of the
2 Agriculture Article when prescribing controlled substances for animals in the usual course
3 of providing professional services;

4 (iv) A pharmacy issued a waiver permit under COMAR 10.34.17.03
5 that provides pharmaceutical specialty services exclusively to persons living in assisted
6 living facilities, comprehensive care facilities, and developmental disabilities facilities; and

7 (v) A pharmacy that:

8 1. Dispenses medications to an inpatient hospice; and

9 2. Has been granted a waiver under § 21–2A–03(f) of this
10 subtitle.

11 (e) “Licensing entity” means an entity authorized under the Health Occupations
12 Article to license, regulate, or discipline a prescriber or dispenser.

13 (f) “Monitored prescription drug” means a prescription drug that contains a
14 Schedule II, Schedule III, Schedule IV, or Schedule V controlled dangerous substance
15 designated under Title 5, Subtitle 4 of the Criminal Law Article.

16 (g) “Opioid [maintenance] **TREATMENT SERVICES** program” means a program
17 that:

18 (1) Is certified **IN ACCORDANCE WITH § 8–401 OF THIS ARTICLE OR**
19 **LICENSED** by the State under [**§ 8–404**] **§ 7.5–401** of this article;

20 (2) Is authorized to treat patients with opioid dependence with a
21 medication approved by the federal Food and Drug Administration for opioid dependence;

22 (3) Complies with:

23 (i) The Code of Federal Regulations 42, Part 8;

24 (ii) COMAR 10.47.02.11; and

25 (iii) Requirements for the secure storage and accounting of opioid
26 medication imposed by the federal Drug Enforcement Administration and the State
27 Division of Drug Control; and

28 (4) Has been granted a certification for operation by the Department, the
29 federal Substance Abuse and Mental Health Services Administration, and the federal
30 Center for Substance Abuse Treatment.

1 **(H) “PHARMACIST” MEANS AN INDIVIDUAL WHO IS LICENSED UNDER TITLE**
2 **12 OF THE HEALTH OCCUPATIONS ARTICLE TO DISPENSE A MONITORED**
3 **PRESCRIPTION DRUG.**

4 **(I) “PHARMACIST DELEGATE” MEANS AN INDIVIDUAL WHO IS:**

5 **(1) AUTHORIZED BY A REGISTERED PHARMACIST TO REQUEST OR**
6 **ACCESS PRESCRIPTION MONITORING DATA; AND**

7 **(2) EMPLOYED BY OR UNDER CONTRACT WITH THE SAME**
8 **PROFESSIONAL PRACTICE AS THE REGISTERED PHARMACIST.**

9 **[(h)] (J) “Prescriber” means a licensed health care professional authorized by**
10 **law to prescribe a monitored prescription drug.**

11 **(K) “PRESCRIBER DELEGATE” MEANS AN INDIVIDUAL WHO IS:**

12 **(1) AUTHORIZED BY A REGISTERED PRESCRIBER TO REQUEST OR**
13 **ACCESS PRESCRIPTION MONITORING DATA; AND**

14 **(2) EMPLOYED BY OR UNDER CONTRACT WITH THE SAME**
15 **PROFESSIONAL PRACTICE AS THE PRESCRIBER.**

16 **[(i)] (L) “Prescription drug” has the meaning stated in § 21–201 of this title.**

17 **[(j)] (M) “Prescription monitoring data” means the information submitted to the**
18 **Program for a monitored prescription drug.**

19 **[(k)] (N) “Program” means the Prescription Drug Monitoring Program**
20 **established under this subtitle.**

21 **(O) “REGISTERED” MEANS REGISTERED WITH THE PROGRAM TO REQUEST**
22 **OR ACCESS PRESCRIPTION MONITORING DATA FOR CLINICAL USE.**

23 **(P) “TERMINAL ILLNESS” MEANS A MEDICAL CONDITION THAT, WITHIN**
24 **REASONABLE MEDICAL JUDGMENT, INVOLVES A PROGNOSIS FOR A PATIENT THAT**
25 **LIKELY WILL RESULT IN THE PATIENT’S DEATH WITHIN 6 MONTHS.**

26 21–2A–02.

27 (b) The mission of the Program is to:

28 (1) Assist prescribers, [dispensers] **PHARMACISTS**, and public health
29 professionals in:

1 (i) The identification and prevention of prescription drug abuse; and

2 (ii) The identification and investigation of unlawful prescription
3 drug diversion; and

4 (2) Promote a balanced use of prescription monitoring data to assist
5 appropriate law enforcement activities while preserving the professional practice of health
6 care providers and the access of patients to optimal pharmaceutical care.

7 (c) To carry out its mission, the Program shall monitor the prescribing and
8 dispensing of all Schedule II, Schedule III, Schedule IV, and Schedule V controlled
9 dangerous substances by all prescribers and dispensers in the State.

10 21-2A-03.

11 (a) The Department shall implement the Program, subject to the availability of
12 funds.

13 (b) The Secretary may:

14 (1) Assign responsibility for the operation of the Program to any unit in the
15 Department; [and]

16 (2) Contract with any qualified person for the efficient and economical
17 operation of the Program; AND

18 **(3) IDENTIFY AND PUBLISH A LIST OF MONITORED PRESCRIPTION**
19 **DRUGS THAT HAVE A LOW POTENTIAL FOR ABUSE BY INDIVIDUALS.**

20 (e) The Secretary, in consultation with the Maryland Health Care Commission
21 and the Board, shall:

22 (1) Determine the appropriate technology to support the operation of the
23 Program; and

24 (2) Educate dispensers, prescribers, **PHARMACISTS, PRESCRIBER**
25 **DELEGATES, PHARMACIST DELEGATES,** and consumers about the purpose and operation
26 of the Program.

27 21-2A-04.

28 (a) The Secretary, in consultation with the Board, shall adopt regulations to carry
29 out this subtitle.

30 (b) The regulations adopted by the Secretary shall:

- 1 (1) Specify the prescription monitoring data required to be submitted
2 under § 21-2A-03 of this subtitle;
- 3 (2) Specify the electronic or other means by which information is to be
4 submitted:
- 5 (i) Without unduly increasing the workload and expense on
6 dispensers; and
- 7 (ii) In a manner as compatible as possible with existing data
8 submission practices of dispensers;
- 9 (3) Specify that the Program:
- 10 (i) Shall provide the information technology software to dispensers
11 necessary to upload prescription drug monitoring data to the Program; and
- 12 (ii) May not impose any fees or other assessments on prescribers or
13 dispensers to support the operation of the Program;
- 14 (4) Specify [that a prescriber or dispenser is not required or obligated to
15 access or use prescription monitoring data available under the Program] **THE**
16 **CIRCUMSTANCES UNDER WHICH A PRESCRIBER OR PHARMACIST IS REQUIRED TO**
17 **REQUEST PRESCRIPTION MONITORING DATA FROM THE PROGRAM, AS PROVIDED**
18 **UNDER § 21-2A-04.2 OF THIS SUBTITLE;**
- 19 (5) Identify the mechanism by which prescription monitoring data are
20 disclosed to a person, in accordance with § 21-2A-06 of this subtitle;
- 21 (6) Identify the circumstances under which a person may disclose
22 prescription monitoring data received under the Program;
- 23 (7) Specify the process for the Program's review of prescription monitoring
24 data and reporting of [possible]:
- 25 **(I) POSSIBLE** misuse or abuse of a monitored prescription drug
26 under § 21-2A-06(c) of this subtitle; **OR**
- 27 **(II) A POSSIBLE VIOLATION OF LAW OR BREACH OF**
28 **PROFESSIONAL STANDARDS UNDER § 21-2A-06(D) OF THIS SUBTITLE;**
- 29 (8) Establish requirements for Program retention of prescription
30 monitoring data for 3 years; and
- 31 (9) Require that:

1 (i) Confidential or privileged patient information be kept
2 confidential; and

3 (ii) Records or information protected by a privilege between a health
4 care provider and a patient, or otherwise required by law to be held confidential, be filed in
5 a manner that, except as otherwise provided in § 21-2A-06 of this subtitle, does not disclose
6 the identity of the person protected.

7 **21-2A-04.1.**

8 (A) A PRESCRIBER SHALL BE REGISTERED WITH THE PROGRAM BEFORE
9 OBTAINING A NEW OR RENEWAL REGISTRATION WITH THE DEPARTMENT UNDER §
10 5-304(A) OF THE CRIMINAL LAW ARTICLE OR BY JULY 1, 2017, WHICHEVER IS
11 SOONER.

12 (B) A PHARMACIST SHALL BE REGISTERED WITH THE PROGRAM BY JULY 1,
13 2017.

14 (C) BEFORE REGISTERING WITH THE PROGRAM, A PRESCRIBER AND A
15 PHARMACIST SHALL COMPLETE A COURSE OF INSTRUCTION AND TRAINING,
16 DEVELOPED IN COOPERATION WITH THE DEPARTMENT, ABOUT:

17 (1) HOW TO USE THE PROGRAM; AND

18 (2) SIGNS OF POSSIBLE MISUSE OR ABUSE OF CONTROLLED
19 DANGEROUS SUBSTANCES.

20 **21-2A-04.2.**

21 (A) (1) BEGINNING JULY 1, 2018, A PRESCRIBER OR PHARMACIST:

22 (I) SHALL REQUEST AT LEAST THE PRIOR 12 MONTHS OF
23 PRESCRIPTION MONITORING DATA FOR A PATIENT BEFORE INITIATING A COURSE
24 OF TREATMENT FOR THE PATIENT THAT INCLUDES PRESCRIBING OR DISPENSING
25 AN OPIOID OR A BENZODIAZEPINE;

26 (II) SHALL, IF A PATIENT'S COURSE OF TREATMENT CONTINUES
27 TO INCLUDE PRESCRIBING OR DISPENSING AN OPIOID OR A BENZODIAZEPINE FOR
28 MORE THAN 90 DAYS AFTER THE INITIAL REQUEST FOR PRESCRIPTION MONITORING
29 DATA, REQUEST PRESCRIPTION MONITORING DATA FOR THE PATIENT AT LEAST
30 EVERY 90 DAYS UNTIL THE COURSE OF TREATMENT HAS ENDED; AND

31 (III) SHALL ASSESS PRESCRIPTION MONITORING DATA
32 REQUESTED FROM THE PROGRAM BEFORE DECIDING WHETHER TO PRESCRIBE OR

1 DISPENSE OR CONTINUE PRESCRIBING OR DISPENSING AN OPIOID OR A
2 BENZODIAZEPINE.

3 (2) IF A PRESCRIBER DECIDES TO PRESCRIBE OR CONTINUE TO
4 PRESCRIBE AN OPIOID OR A BENZODIAZEPINE AFTER REQUESTING PRESCRIPTION
5 MONITORING DATA FROM THE PROGRAM AND ASSESSING THE PRESCRIPTION
6 MONITORING DATA, THE PRESCRIBER SHALL DOCUMENT IN THE PATIENT'S
7 MEDICAL RECORD THAT THE PRESCRIPTION MONITORING DATA WAS REQUESTED
8 AND ASSESSED.

9 (B) A PRESCRIBER OR PHARMACIST MAY AUTHORIZE A PRESCRIBER
10 DELEGATE OR PHARMACIST DELEGATE TO REQUEST PRESCRIPTION MONITORING
11 DATA ON BEHALF OF THE PRESCRIBER OR PHARMACIST IF:

12 (1) THE PRESCRIBER OR PHARMACIST TAKES REASONABLE STEPS TO
13 ENSURE THAT THE PRESCRIBER DELEGATE OR PHARMACIST DELEGATE IS
14 COMPETENT IN THE USE OF THE PROGRAM;

15 (2) THE PRESCRIBER OR PHARMACIST REMAINS RESPONSIBLE FOR:

16 (I) ENSURING THAT ACCESS TO THE PROGRAM BY THE
17 PRESCRIBER DELEGATE OR PHARMACIST DELEGATE IS LIMITED TO PURPOSES
18 AUTHORIZED BY LAW;

19 (II) PROTECTING THE CONFIDENTIALITY OF THE
20 PRESCRIPTION MONITORING DATA; AND

21 (III) ANY BREACH OF CONFIDENTIALITY BY THE PRESCRIBER
22 DELEGATE OR PHARMACIST DELEGATE; AND

23 (3) THE DECISION WHETHER TO PRESCRIBE OR DISPENSE A
24 MONITORED PRESCRIPTION DRUG FOR A PATIENT:

25 (I) REMAINS WITH THE PRESCRIBER OR PHARMACIST; AND

26 (II) IS REASONABLY INFORMED BY THE PRESCRIPTION
27 MONITORING DATA OBTAINED FROM THE PROGRAM.

28 (C) A PRESCRIBER OR PHARMACIST IS NOT REQUIRED TO REQUEST
29 PRESCRIPTION MONITORING DATA FROM THE PROGRAM IF THE OPIOID OR
30 BENZODIAZEPINE IS PRESCRIBED OR DISPENSED TO AN INDIVIDUAL:

31 (1) IN AN AMOUNT INDICATED FOR A PERIOD NOT TO EXCEED 7 DAYS;

1 **(2) FOR THE TREATMENT OF CANCER OR ANOTHER CONDITION**
2 **ASSOCIATED WITH CANCER;**

3 **(3) WHO IS:**

4 **(I) A PATIENT TREATED AT AN INSTITUTION OF**
5 **POSTSECONDARY EDUCATION TO THE EXTENT THAT IT PROVIDES INSTRUCTION TO**
6 **INDIVIDUALS PREPARING TO PRACTICE AS PHYSICIANS, PODIATRISTS, DENTISTS,**
7 **NURSES, PHYSICIAN ASSISTANTS, OPTOMETRISTS, OR VETERINARIANS;**

8 **(II) A PATIENT AT A HOSPITAL, INCLUDING ANY:**

9 **1. OUTPATIENT FACILITY;**

10 **2. CLINIC OF A HOSPITAL; OR**

11 **3. OFFICE OF A HOSPITAL-EMPLOYED HEALTH CARE**
12 **PRACTITIONER, TO THE EXTENT THAT THE HEALTH CARE PRACTITIONER**
13 **PRACTICES AT THE OFFICE AS A HOSPITAL EMPLOYEE;**

14 **(III) 1. A PATIENT AT A HOSPICE CARE FACILITY LICENSED**
15 **UNDER TITLE 19, SUBTITLE 9 OF THIS ARTICLE; OR**

16 **2. ANY OTHER PATIENT DIAGNOSED WITH A TERMINAL**
17 **ILLNESS;**

18 **(IV) A PATIENT AT A FACILITY MAINTAINED OR OPERATED BY**
19 **THE STATE;**

20 **(V) A PATIENT AT A NURSING FACILITY LICENSED UNDER TITLE**
21 **19, SUBTITLE 3 OF THIS ARTICLE;**

22 **(VI) A PATIENT AT A CLINIC MAINTAINED OR OPERATED BY THE**
23 **FEDERAL GOVERNMENT; OR**

24 **(VII) A PATIENT AT A CLINIC, FACILITY, OR PRACTICE AT WHICH**
25 **THE USE OF OPIOIDS OR BENZODIAZEPINES FOR A MAJORITY OF THE PATIENTS IS**
26 **FOR TREATMENT FOR PAIN IMMEDIATELY BEFORE, DURING, AND NOT MORE THAN**
27 **14 DAYS AFTER SURGERY; OR**

28 **(4) TO TREAT ACUTE PAIN RESULTING FROM A SURGICAL OR OTHER**
29 **INVASIVE PROCEDURE OR CHILDBIRTH.**

1 **(D) A PRESCRIBER OR PHARMACIST MAY NOT BE REQUIRED TO COMPLY**
2 **WITH THE PROVISIONS OF THIS SECTION WHEN:**

3 **(1) PRESCRIBING OR DISPENSING AN OPIOID OR A BENZODIAZEPINE**
4 **DRUG THAT HAS BEEN LISTED BY THE SECRETARY UNDER § 21-2A-03(B)(3) OF THIS**
5 **SUBTITLE AS HAVING A LOW POTENTIAL FOR ABUSE;**

6 **(2) ACCESSING PRESCRIPTION MONITORING DATA WOULD RESULT IN**
7 **A DELAY IN THE TREATMENT OF A PATIENT THAT WOULD NEGATIVELY IMPACT THE**
8 **MEDICAL CONDITION OF THE PATIENT;**

9 **(3) ELECTRONIC ACCESS TO PRESCRIPTION MONITORING DATA IS**
10 **NOT OPERATIONAL AS DETERMINED BY THE DEPARTMENT; OR**

11 **(4) PRESCRIPTION MONITORING DATA CANNOT BE ACCESSED BY THE**
12 **PRESCRIBER OR PHARMACIST DUE TO A TEMPORARY TECHNOLOGICAL OR**
13 **ELECTRICAL FAILURE, AS DESCRIBED IN REGULATION.**

14 **(E) IF A PRESCRIBER OR PHARMACIST DOES NOT ACCESS PRESCRIPTION**
15 **MONITORING DATA FOR ANY OF THE REASONS PROVIDED UNDER SUBSECTION**
16 **(D)(2), (3), OR (4) OF THIS SECTION:**

17 **(1) THE PRESCRIBER OR PHARMACIST SHALL USE REASONABLE**
18 **MEDICAL JUDGMENT IN DETERMINING WHETHER TO PRESCRIBE OR DISPENSE AN**
19 **OPIOID OR A BENZODIAZEPINE; AND**

20 **(2) THE PRESCRIBER SHALL ENTER AN APPROPRIATE RECORD IN**
21 **THE PATIENT'S MEDICAL CHART, INCLUDING THE REASON WHY PRESCRIPTION**
22 **MONITORING DATA WAS NOT ACCESSED.**

23 21-2A-05.

24 (f) The Board shall:

25 (3) Provide annually to the Governor and, in accordance with § 2-1246 of
26 the State Government Article, the General Assembly a report that includes:

27 (i) The number of prescribers **AND PRESCRIBER DELEGATES**
28 registered with and using the Program;

29 (ii) The number of [dispensers] **PHARMACISTS AND PHARMACIST**
30 **DELEGATES** registered with and using the Program;

1 21–2A–06.

2 (a) Prescription monitoring data:

3 (1) Are confidential and privileged, and not subject to discovery, subpoena,
4 or other means of legal compulsion in civil litigation;

5 (2) Are not public records; and

6 (3) Except as provided in subsections (b), (c), **(D)**, and **[(e)] (F)** of this
7 section or as otherwise provided by law, may not be disclosed to any person.

8 (b) The Program shall disclose prescription monitoring data, in accordance with
9 regulations adopted by the Secretary, to:

10 (1) A prescriber, or a licensed health care practitioner authorized by the
11 prescriber, in connection with the medical care of a patient;

12 (2) A dispenser, or a licensed health care practitioner authorized by the
13 dispenser, in connection with the dispensing of a monitored prescription drug;

14 (3) A federal law enforcement agency or a State or local law enforcement
15 agency, on issuance of a subpoena, for the purpose of furthering an existing bona fide
16 individual investigation;

17 (4) The State Board of Physicians, on issuance of an administrative
18 subpoena voted on by a quorum of a disciplinary panel, as defined in § 14–101 of the Health
19 Occupations Article, for the purposes of furthering an existing bona fide investigation of an
20 individual;

21 (5) A licensing entity other than the State Board of Physicians, on issuance
22 of an administrative subpoena voted on by a quorum of the board of the licensing entity,
23 for the purposes of furthering an existing bona fide individual investigation;

24 (6) A rehabilitation program under a health occupations board, on issuance
25 of an administrative subpoena;

26 (7) A patient with respect to prescription monitoring data about the
27 patient;

28 (8) Subject to subsection **[(h)] (I)** of this section, the authorized
29 administrator of another state's prescription drug monitoring program;

30 (9) The following units of the Department, on approval of the Secretary, for
31 the purpose of furthering an existing bona fide individual investigation:

32 (i) The Office of the Chief Medical Examiner;

1 (ii) The Maryland Medical Assistance Program;

2 (iii) The Office of the Inspector General;

3 (iv) The Office of Health Care Quality; and

4 (v) The Division of Drug Control;

5 (10) The technical advisory committee established under § 21–2A–07 of this
6 subtitle for the purposes set forth in subsections (c) and [(d)] (E) of this section; or

7 (11) The following entities, on approval of the Secretary and for the purpose
8 of furthering an existing bona fide individual case review:

9 (i) The State Child Fatality Review Team or a local child fatality
10 review team established under Title 5, Subtitle 7 of this article, on request from the chair
11 of the State or local team;

12 (ii) A local drug overdose fatality review team established under §
13 5–902 of this article, on request from the chair of the local team;

14 (iii) The Maternal Mortality Review Program established under §
15 13–1203 of this article, on request from the Program; and

16 (iv) A medical review committee described in § 1–401(b)(3) of the
17 Health Occupations Article, on request from the committee.

18 (c) (1) In accordance with regulations adopted by the Secretary:

19 (i) The Program [may] **SHALL** review prescription monitoring data
20 for indications of possible misuse or abuse of a monitored prescription drug; and

21 (ii) If the Program’s review of prescription monitoring data indicates
22 possible misuse or abuse of a monitored prescription drug, the Program [may] **SHALL**
23 report the possible misuse or abuse to the prescriber [or dispenser] of the monitored
24 prescription drug **OR THE PHARMACIST WHO DISPENSED THE MONITORED**
25 **PRESCRIPTION DRUG.**

26 (2) Before the Program reports the possible misuse or abuse of a monitored
27 prescription drug to a prescriber or dispenser under this subsection, the Program shall
28 obtain from the technical advisory committee:

29 (i) Clinical guidance regarding indications of possible misuse or
30 abuse; and

1 (ii) Interpretation of the prescription monitoring data that indicates
2 possible misuse or abuse.

3 (D) (1) IN ACCORDANCE WITH REGULATIONS ADOPTED BY THE
4 SECRETARY, THE PROGRAM SHALL REVIEW PRESCRIPTION MONITORING DATA FOR
5 INDICATIONS OF A POSSIBLE VIOLATION OF LAW OR A BREACH OF PROFESSIONAL
6 STANDARDS BY A PRESCRIBER OR A PHARMACIST.

7 (2) IF THE PROGRAM'S REVIEW INDICATES A POSSIBLE VIOLATION OF
8 LAW OR BREACH OF PROFESSIONAL STANDARDS BY A PRESCRIBER OR A
9 PHARMACIST, THE PROGRAM SHALL:

10 (I) NOTIFY THE APPROPRIATE LICENSING ENTITY OR LAW
11 ENFORCEMENT AGENCY; AND

12 (II) PROVIDE INFORMATION NECESSARY TO THE LICENSING
13 ENTITY OR LAW ENFORCEMENT AGENCY TO CARRY OUT AN INVESTIGATION.

14 [(d)] (E) (1) Before the Program discloses information under subsection
15 (b)(3), (4), (5), [(7), or (8)] (6), OR (9) of this section, the technical advisory committee shall:

16 (i) Review the requests for information;

17 (ii) Provide clinical guidance and interpretation of the information
18 requested to the Secretary to assist in the Secretary's decision on how to respond to a
19 judicial subpoena, administrative subpoena, or other request; and

20 (iii) Provide clinical guidance and interpretation of the information
21 requested to the authorized recipient of the information.

22 (2) Notwithstanding paragraph (1) of this subsection, the Program may
23 disclose information to the authorized administrator of another state's prescription drug
24 monitoring program for disclosure to the persons listed in subsection (b)(1), (2), and (6) of
25 this section without the review, clinical guidance, and interpretation of the technical
26 advisory committee.

27 [(e)] (F) Except as provided by regulations adopted by the Secretary, a person
28 who receives prescription monitoring data from the Program may not disclose the data.

29 [(f)] (G) (1) In addition to the disclosures required under subsection (b) of
30 this section, the Program may disclose prescription monitoring data for research, analysis,
31 public reporting, and education:

32 (i) After redaction of all information that could identify a patient,
33 prescriber, dispenser, or any other individual; and

1 (ii) In accordance with regulations adopted by the Secretary.

2 (2) The Secretary may require submission of an abstract explaining the
3 scope and purpose of the research, analysis, public reporting, or education before disclosing
4 prescription monitoring data under this subsection.

5 **[(g)] (H)** The Office of the Attorney General may seek appropriate injunctive or
6 other relief to maintain the confidentiality of prescription monitoring data as required
7 under this section.

8 **[(h)] (I)** The Program may provide prescription monitoring data to another
9 state's prescription drug monitoring program only if the other state's prescription drug
10 monitoring program agrees to use the prescription monitoring data in a manner consistent
11 with the provisions of this subtitle.

12 **[(i)] (J)** The Program may:

13 (1) Request and receive prescription monitoring data from another state's
14 prescription drug monitoring program and use the prescription monitoring data in a
15 manner consistent with the provisions of this subtitle; and

16 (2) Develop the capability to transmit prescription monitoring data to and
17 receive prescription monitoring data from other prescription drug monitoring programs
18 employing the standards of interoperability.

19 **[(j)] (K)** The Program may enter into written agreements with other states'
20 prescription drug monitoring programs for the purpose of establishing the terms and
21 conditions for sharing prescription monitoring data under this section.

22 **[(k)] (L)** Prescription monitoring data may not be used as the basis for imposing
23 clinical practice standards.

24 21-2A-07.

25 (b) The purpose the technical advisory committee is to:

26 (1) Review requests for information from the Program under §
27 21-2A-06(b)(3), (5), (6), **[(8) and] OR** (9) of this subtitle; and

28 (2) Provide clinical guidance and interpretation to the Program regarding
29 indications of possible misuse or abuse of a monitored prescription drug under §
30 21-2A-06(c)(2) of this subtitle.

31 21-2A-08.

1 (b) **[A] EXCEPT AS PROVIDED IN § 21-2A-09(B)(3) OF THIS SUBTITLE, A**
2 prescriber [or dispenser], **PRESCRIBER DELEGATE, PHARMACIST, OR PHARMACIST**
3 **DELEGATE**, acting in good faith, is not subject to liability or disciplinary action arising
4 solely from:

5 (1) Requesting or receiving, or failing to request or receive, prescription
6 monitoring data from the Program; or

7 (2) Acting, or failing to act, on the basis of prescription monitoring data
8 provided by the Program.

9 21-2A-09.

10 (a) A dispenser who knowingly fails to submit prescription monitoring data to the
11 Program as required under this subtitle shall be subject to a civil penalty not exceeding
12 \$500 for each failure to submit required information.

13 (b) (1) A person who knowingly discloses, uses, obtains, or attempts to obtain
14 by fraud or deceit, prescription monitoring data in violation of this subtitle shall be guilty
15 of a misdemeanor and on conviction is subject to imprisonment not exceeding 1 year or a
16 fine not exceeding \$10,000 or both.

17 (2) In addition to the penalties under paragraph (1) of this subsection, a
18 prescriber [or dispenser], **PRESCRIBER DELEGATE, PHARMACIST, OR PHARMACIST**
19 **DELEGATE** who knowingly discloses or uses prescription monitoring data in violation of
20 this subtitle shall be subject to disciplinary action by the appropriate licensing entity.

21 **(3) A PRESCRIBER OR PHARMACIST WHO VIOLATES § 21-2A-04.1 OR**
22 **§ 21-2A-04.2 OF THIS SUBTITLE SHALL BE SUBJECT TO DISCIPLINARY ACTION BY**
23 **THE APPROPRIATE LICENSING ENTITY.**

24 **[(3)] (4)** The release of prescription monitoring data by a prescriber [or
25 dispenser], **PRESCRIBER DELEGATE, PHARMACIST, OR PHARMACIST DELEGATE** to a
26 licensed health care professional solely for treatment purposes in a manner otherwise
27 consistent with State and federal law is not a violation of this subtitle.

28 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
29 October 1, 2016.