SENATE BILL 537

J1, J2 (6lr3249)

ENROLLED BILL

— Finance/Health and Government Operations —

Introduced by ~~**Senator Klausmeier**~~ **Senators Klausmeier, Astle, Benson, Feldman, Hershey, Jennings, Kelley, Mathias, Middleton, Pugh, and Reilly**

Read and Examined by Proofreaders:

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Proofreader.

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Proofreader.

Sealed with the Great Seal and presented to the Governor, for his approval this _____ day of _____ at _____ o'clock, _____M.

_____

President.

CHAPTER _____

AN ACT concerning

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

FOR the purpose of requiring that certain authorized providers ~~and prescribers~~ be registered with the Prescription Drug Monitoring Program before obtaining a certain new or renewal registration ~~or by a certain date, whichever is sooner~~; requiring that certain prescribers be registered with the Program before obtaining a certain new or renewal registration or by a certain date, whichever is sooner; requiring that certain pharmacists be registered with the Program by a certain date; requiring a prescriber and a pharmacist to complete a certain course of instruction before registering with the Program; altering the mission of the Program; authorizing the Secretary of Health and Mental Hygiene to identify and publish a list of certain monitored prescription drugs; requiring the Secretary, in consultation with the Maryland Health Care Commission and the Advisory Board on Prescription Drug Monitoring,

EXPLANATION: **CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.**
[Brackets**]** indicate matter deleted from existing law.
Underlining indicates amendments to bill.
~~Strike out~~ indicates matter stricken from the bill by amendment or deleted from the law by amendment.
Italics indicate opposite chamber/conference committee amendments.

to educate pharmacists, prescriber delegates, and pharmacist delegates about the purpose and operation of the Program; requiring certain regulations adopted by the Secretary to specify a certain frequency for dispensers to submit certain information; ~~altering~~ repealing a requirement that certain regulations adopted by the Secretary specify that a prescriber or dispenser is not required or obligated to access or use certain prescription monitoring data ~~to instead require the regulations to specify the circumstances under which a prescriber or a pharmacist is required to request prescription monitoring data from the Program~~; requiring that certain regulations adopted by the Secretary specify a process for the Program's review of prescription monitoring data and reporting of a possible violation of law or possible breach of professional standards; requiring certain prescribers ~~and pharmacists~~ to request and assess certain prescription monitoring data under certain circumstances; requiring a certain prescriber to document certain information in a patient's medical records under certain circumstances; authorizing a certain prescriber or pharmacist to authorize a prescriber delegate or pharmacist delegate to request prescription monitoring data on behalf of the prescriber or pharmacist under certain circumstances; specifying the circumstances under which certain prescribers ~~and pharmacists~~ are not required to request prescription monitoring data from the Program or to comply with certain provisions of this Act; requiring certain prescribers ~~and pharmacists~~ who do not access prescription monitoring data to take certain actions; requiring a pharmacist or pharmacist delegate to request prescription monitoring data before dispensing a monitored prescription drug under certain circumstances and for a certain purpose; providing that a pharmacist shall have the responsibility described in a certain federal regulation; authorizing the Secretary to adopt regulations regarding certain exemptions; ~~requiring, instead of authorizing, the Program to review prescription monitoring data for signs of certain misuse or abuse and requiring, instead of authorizing, the Program to report the possible misuse or abuse to a certain prescriber or pharmacist; requiring~~ authorizing, instead of requiring, the Program to obtain from a certain technical advisory committee certain guidance and interpretation of certain data; authorizing the Program to review prescription monitoring data for indications of a possible violation of law or a possible breach of professional standards by a prescriber or a ~~pharmacist~~ dispenser; ~~requiring~~ authorizing the Program to provide certain notification and ~~information~~ education under certain circumstances; requiring the Program to obtain certain guidance and certain interpretation of certain data before providing certain notification of certain possible violations; authorizing the Program, under certain circumstances, to request that a certain technical advisory committee review certain requests and provide certain clinical guidance; requiring the Program, in consultation with the Advisory Board on Prescription Drug Monitoring, to consider certain policies and procedures; altering the information that the Advisory Board on Prescription Drug Monitoring must report annually to the Governor and the General Assembly; altering the purpose and membership of a certain technical advisory committee; altering a certain immunity from liability or disciplinary action arising solely from certain actions; providing that prescribers, prescriber delegates, pharmacists, and pharmacist delegates shall be subject to disciplinary action by the appropriate licensing entity for certain violations; providing that a release of prescription monitoring data by a prescriber delegate, pharmacist, or pharmacist

delegate under certain circumstances is not a violation of certain provisions of law; requiring the Department of Health and Mental Hygiene to report to certain committees, on or before certain dates, regarding the ongoing implementation and use of the Program; requiring the Department to report to certain committees, on or before a certain date, on certain matters, for a certain purpose; requiring the Department to develop and implement a certain plan; making certain provisions of this Act subject to certain contingencies; requiring the Secretary to give certain notice to the Department of Legislative Services and certain committees of the General Assembly within a certain time period after the Secretary makes a determination that certain contingencies have been satisfied; providing that certain provisions of this Act shall be null and void under certain circumstances; altering certain definitions; defining certain terms; making certain technical corrections; and generally relating to the Prescription Drug Monitoring Program.

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

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

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

BY adding to
Article – Health – General
Section 21–2A–01(h), (i), (k), (o), and (p), 21–2A–04.1, ~~and~~ 21–2A–04.2, and 21–2A–04.3
Annotated Code of Maryland
(2015 Replacement Volume)

BY repealing and reenacting, with amendments,
Article – Health – General
Section 21–2A–09(b)(3)
Annotated Code of Maryland
(2015 Replacement Volume)
(As enacted by Section 4 of this Act)

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

Article – Criminal Law

5–304.

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

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

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

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

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

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

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

Article – Health – General

21–2A–01.

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

(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;

(ii) An opioid **[**maintenance**]** **TREATMENT SERVICES** 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. Dispenses medications to an inpatient 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**]** **TREATMENT SERVICES** program" means a program that:

(1) Is certified **IN ACCORDANCE WITH § 8–401 OF THIS ARTICLE OR LICENSED** by the State under **[**§ 8–404**]** **§ 7.5–401** 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.

(H) "PHARMACIST" MEANS AN INDIVIDUAL WHO IS LICENSED UNDER TITLE 12 OF THE HEALTH OCCUPATIONS ARTICLE TO DISPENSE A MONITORED PRESCRIPTION DRUG.

(I) "PHARMACIST DELEGATE" MEANS AN INDIVIDUAL WHO IS:

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

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

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

(K) "PRESCRIBER DELEGATE" MEANS AN INDIVIDUAL WHO IS:

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

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

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

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

[(k)**] (N)** "Program" means the Prescription Drug Monitoring Program established under this subtitle.

(O) "REGISTERED" MEANS REGISTERED WITH THE PROGRAM TO REQUEST OR ACCESS PRESCRIPTION MONITORING DATA FOR CLINICAL USE.

(P) "TERMINAL ILLNESS" MEANS A MEDICAL CONDITION THAT, WITHIN REASONABLE MEDICAL JUDGMENT, INVOLVES A PROGNOSIS FOR A PATIENT THAT LIKELY WILL RESULT IN THE PATIENT'S DEATH WITHIN 6 MONTHS.

21–2A–02.

(b) The mission of the Program is to:

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

(i) The identification 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**; AND**

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

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

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

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

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

(ii) In a manner as compatible as possible with existing data submission practices of dispensers;

(3) SPECIFY THAT THE INFORMATION BE SUBMITTED BY DISPENSERS ONCE EVERY 24 HOURS;

~~(3)~~ **(4)** 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;

~~(4) Specify [that a prescriber or dispenser is not required or obligated to access or use prescription monitoring data available under the Program] THE CIRCUMSTANCES UNDER WHICH A PRESCRIBER OR PHARMACIST IS REQUIRED TO REQUEST PRESCRIPTION MONITORING DATA FROM THE PROGRAM, AS PROVIDED UNDER § 21–2A–04.2 OF THIS SUBTITLE;~~

(5) Identify the mechanism by which prescription monitoring data are disclosed to a person, in accordance with § 21–2A–06 of this subtitle;

(6) Identify the circumstances under which a person may disclose prescription monitoring data received under the Program;

(7) Specify the process for the Program's review of prescription monitoring data and reporting of **[**possible**]:**

(I) **POSSIBLE** misuse or abuse of a monitored prescription drug under § 21–2A–06(c) of this subtitle; **OR**

(II) A POSSIBLE VIOLATION OF LAW OR <u>POSSIBLE</u> BREACH OF PROFESSIONAL STANDARDS UNDER § 21–2A–06(D) OF THIS SUBTITLE;

(8) Establish requirements for Program retention of prescription monitoring data for 3 years; and

(9) 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–06 of this subtitle, does not disclose the identity of the person protected.

21–2A–04.1.

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

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

(C) BEFORE REGISTERING WITH THE PROGRAM, A PRESCRIBER AND A PHARMACIST SHALL COMPLETE A COURSE OF INSTRUCTION AND TRAINING <u>DEVELOPED BY THE DEPARTMENT</u>, ~~DEVELOPED IN COOPERATION WITH THE DEPARTMENT, ABOUT:~~

~~(1) HOW TO USE THE PROGRAM; AND~~

~~(2) SIGNS OF POSSIBLE MISUSE OR ABUSE OF CONTROLLED DANGEROUS SUBSTANCES~~ <u>INCLUDING THE EFFECTIVE USE OF THE PROGRAM</u>.

<u>SECTION 3. AND BE IT FURTHER ENACTED, That the Laws of Maryland read as follows:</u>

<u>Article – Health – General</u>

21–2A–04.2.

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

(I) SHALL REQUEST AT LEAST THE PRIOR ~~12~~ 4 MONTHS OF PRESCRIPTION MONITORING DATA FOR A PATIENT BEFORE INITIATING A COURSE OF TREATMENT FOR THE PATIENT THAT INCLUDES PRESCRIBING OR DISPENSING AN OPIOID OR A BENZODIAZEPINE;

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

(III) SHALL ASSESS PRESCRIPTION MONITORING DATA REQUESTED FROM THE PROGRAM BEFORE DECIDING WHETHER TO PRESCRIBE OR DISPENSE OR CONTINUE PRESCRIBING OR DISPENSING AN OPIOID OR A BENZODIAZEPINE.

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

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

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

~~**(2) THE PRESCRIBER OR PHARMACIST REMAINS RESPONSIBLE FOR:**~~

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

~~**(II) PROTECTING THE CONFIDENTIALITY OF THE PRESCRIPTION MONITORING DATA; AND**~~

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

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

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

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

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

(1) IN AN AMOUNT INDICATED FOR A PERIOD NOT TO EXCEED ~~7~~ 3 DAYS;

(2) FOR THE TREATMENT OF CANCER OR ~~ANOTHER CONDITION ASSOCIATED WITH CANCER~~ CANCER–RELATED PAIN;

(3) WHO IS:

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

~~(II)~~ A PATIENT ~~AT A~~ RECEIVING TREATMENT IN AN INPATIENT UNIT OF A HOSPITAL~~, INCLUDING ANY:~~

~~1. OUTPATIENT FACILITY;~~

~~2. CLINIC OF A HOSPITAL; OR~~

~~3. OFFICE OF A HOSPITAL–EMPLOYED HEALTH CARE PRACTITIONER, TO THE EXTENT THAT THE HEALTH CARE PRACTITIONER PRACTICES AT THE OFFICE AS A HOSPITAL EMPLOYEE~~;

~~(III)~~ (II) 1. A PATIENT ~~AT A HOSPICE CARE FACILITY LICENSED UNDER TITLE 19, SUBTITLE 9~~ IN A GENERAL HOSPICE CARE PROGRAM AS DEFINED IN § 19–901 OF THIS ARTICLE; OR

2. ANY OTHER PATIENT DIAGNOSED WITH A TERMINAL ILLNESS;

~~(IV)~~ (III) A PATIENT ~~AT A FACILITY MAINTAINED OR OPERATED BY THE STATE;~~

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

~~(VI) A PATIENT AT A CLINIC MAINTAINED OR OPERATED BY THE FEDERAL GOVERNMENT; OR~~

~~(VII) A PATIENT AT A CLINIC, FACILITY, OR PRACTICE AT WHICH THE USE OF OPIOIDS OR BENZODIAZEPINES FOR A MAJORITY OF THE PATIENTS IS FOR TREATMENT FOR PAIN IMMEDIATELY BEFORE, DURING, AND NOT MORE THAN 14 DAYS AFTER SURGERY~~ WHO RESIDES IN:

1. AN ASSISTED LIVING FACILITY;

2. A LONG–TERM CARE FACILITY;

3. A COMPREHENSIVE CARE FACILITY; OR

4. A DEVELOPMENTAL DISABILITIES FACILITY; OR

(4) TO TREAT OR PREVENT ACUTE PAIN ~~RESULTING FROM A SURGICAL OR OTHER INVASIVE PROCEDURE OR CHILDBIRTH~~ FOR A PERIOD OF NOT MORE THAN 14 DAYS FOLLOWING:

(I) A SURGICAL PROCEDURE IN WHICH GENERAL ANESTHESIA WAS USED;

(II) A FRACTURE;

(III) SIGNIFICANT TRAUMA; OR

(IV) CHILDBIRTH.

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

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

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

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

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

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

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

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

(E) IF A PHARMACIST OR PHARMACIST DELEGATE HAS A REASONABLE BELIEF THAT A PATIENT MAY BE SEEKING A MONITORED PRESCRIPTION DRUG FOR ANY PURPOSE OTHER THAN THE TREATMENT OF AN EXISTING MEDICAL CONDITION:

(1) BEFORE DISPENSING A MONITORED PRESCRIPTION DRUG TO THE PATIENT, THE PHARMACIST OR PHARMACIST DELEGATE SHALL REQUEST PRESCRIPTION MONITORING DATA TO DETERMINE IF THE PATIENT HAS RECEIVED OTHER PRESCRIPTIONS THAT INDICATE MISUSE, ABUSE, OR DIVERSION OF A MONITORED PRESCRIPTION DRUG; AND

(2) THE PHARMACIST SHALL HAVE THE RESPONSIBILITY DESCRIBED IN 21 C.F.R. § 1306.04.

(F) THE SECRETARY MAY ADOPT REGULATIONS TO PROVIDE ADDITIONAL CLINICAL, TECHNICAL, OR ADMINISTRATIVE EXEMPTIONS BASED ON NEW STANDARDS OF PRACTICE.

21–2A–09.

(b) (3) A prescriber or pharmacist who violates § 21–2A–04.1 ***OR § 21–2A–04.2*** *of this subtitle shall be subject to disciplinary action by the appropriate licensing entity.*

SECTION 4. AND BE IT FURTHER ENACTED, That the Laws of Maryland read as follows:

Article – Health – General

21–2A–04.3.

A PRESCRIBER OR PHARMACIST MAY AUTHORIZE A PRESCRIBER DELEGATE OR PHARMACIST DELEGATE TO REQUEST PRESCRIPTION MONITORING DATA ON BEHALF OF THE PRESCRIBER OR PHARMACIST IF:

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

(2) THE PRESCRIBER OR PHARMACIST REMAINS RESPONSIBLE FOR:

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

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

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

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

(I) REMAINS WITH THE PRESCRIBER OR PHARMACIST; AND

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

21–2A–05.

(f) The Board shall:

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

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

(ii) The number of **[**dispensers**]** **PHARMACISTS AND PHARMACIST DELEGATES** registered with and using 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), (c), **(D),** and **[**(e)**] (F)** 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 adopted by the Secretary, to:

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

(2) A dispenser, or a licensed health care practitioner 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) The State Board of Physicians, on issuance of an administrative subpoena voted on by a quorum of a disciplinary panel, as defined in § 14–101 of the Health Occupations Article, for the purposes of furthering an existing bona fide investigation of an individual;

(5) A licensing entity other than the State Board of Physicians, 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;

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

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

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

(9) 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;

(iv) The Office of Health Care Quality; and

(v) The Division of Drug Control;

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

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

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

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

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

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

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

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

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

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

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

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

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

(2) ~~IF~~ SUBJECT TO PARAGRAPH (3) OF THIS SUBSECTION, IF THE PROGRAM'S REVIEW INDICATES A POSSIBLE VIOLATION OF LAW OR A POSSIBLE BREACH OF PROFESSIONAL STANDARDS BY A PRESCRIBER OR A ~~PHARMACIST~~ DISPENSER, THE PROGRAM ~~SHALL~~ MAY:

(I) NOTIFY THE ~~APPROPRIATE LICENSING ENTITY OR LAW ENFORCEMENT AGENCY~~ PRESCRIBER OR DISPENSER OF THE POSSIBLE VIOLATION OF LAW OR POSSIBLE BREACH OF PROFESSIONAL STANDARDS; AND

(II) PROVIDE ~~INFORMATION NECESSARY TO THE LICENSING ENTITY OR LAW ENFORCEMENT AGENCY TO CARRY OUT AN INVESTIGATION~~ EDUCATION TO THE PRESCRIBER OR DISPENSER.

(3) BEFORE THE PROGRAM PROVIDES NOTIFICATION OF A POSSIBLE VIOLATION OF LAW OR A POSSIBLE BREACH OF PROFESSIONAL STANDARDS TO A PRESCRIBER OR A DISPENSER, THE PROGRAM SHALL OBTAIN FROM THE TECHNICAL ADVISORY COMMITTEE:

(I) CLINICAL GUIDANCE REGARDING INDICATIONS OF A POSSIBLE VIOLATION OF LAW OR A POSSIBLE BREACH OF PROFESSIONAL STANDARDS; AND

(II) INTERPRETATION OF THE PRESCRIPTION MONITORING DATA THAT INDICATES A POSSIBLE VIOLATION OF LAW OR A POSSIBLE BREACH OF PROFESSIONAL STANDARDS.

[(d)**] (E)** (1) Before the Program discloses information under subsection (b)(3), (4), (5), **[**(7), or (8)**] (6), (8), OR (9)** of this section, **THE PROGRAM MAY REQUEST THAT** the technical advisory committee ~~shall~~:

(i) Review the requests for information;

(ii) 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

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

(2) ~~Notwithstanding paragraph (1) of this subsection, the Program may disclose information to the authorized administrator of another state's prescription drug monitoring program for disclosure to the persons listed in subsection (b)(1), (2), and (6) of this section without the review, clinical guidance, and interpretation of the technical advisory committee~~ **THE PROGRAM, IN CONSULTATION WITH THE BOARD, SHALL CONSIDER POLICIES AND PROCEDURES FOR DETERMINING THE CIRCUMSTANCES IN WHICH THE REVIEW OF REQUESTS FOR INFORMATION AND THE PROVISION OF CLINICAL GUIDANCE AND INTERPRETATION OF INFORMATION BY THE TECHNICAL ADVISORY COMMITTEE UNDER PARAGRAPH (1) OF THIS SUBSECTION IS FEASIBLE AND DESIRABLE**.

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

[(f)**] (G)** (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.

[(g)**] (H)** 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.

[(h)**] (I)** The Program may provide prescription monitoring data to another state's prescription drug monitoring program 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.

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

(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

(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.

[(j)**] (K)** 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.

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

21–2A–07.

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

(1) Review requests for information from the Program under § 21–2A–06(b)(3), **(4),** (5), (6), ~~[~~(8)**,** ~~and~~**]** **OR** (9) of this subtitle; and

(2) Provide clinical guidance and interpretation to the Program regarding indications of possible misuse or abuse of a monitored prescription drug **OR A POSSIBLE VIOLATION OF LAW OR A POSSIBLE BREACH OF PROFESSIONAL STANDARDS BY A PRESCRIBER OR A DISPENSER** under § ~~21–2A–06(c)(2)~~ **21–2A–06(C) AND (D)** of this subtitle.

(c) The technical advisory committee consists of **[**the following members,**]** **MEMBERS** appointed by the Secretary**, INCLUDING**:

(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**;**

(6) TWO MEDICAL PROFESSIONALS, LICENSED AND PRACTICING IN THE STATE WITH EXPERTISE OR EXPERIENCE IN PROVIDING CARE FOR PATIENTS WITH SUBSTANCE–RELATED OR MENTAL HEALTH DISORDERS;

(7) A DENTIST LICENSED AND PRACTICING IN THE STATE; AND

(8) A MEDICAL PROFESSIONAL LICENSED AND PRACTICING IN THE STATE IN THE FIELD OF INTERNAL MEDICINE OR FAMILY PRACTICE.

21–2A–08.

(b) **[**A**] EXCEPT AS PROVIDED IN § 21–2A–09(B)(3) OF THIS SUBTITLE, A** prescriber **[**or dispenser**]**, **PRESCRIBER DELEGATE, PHARMACIST, OR PHARMACIST DELEGATE,** 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.

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) (1) A person who knowingly 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**], PRESCRIBER DELEGATE, PHARMACIST, OR PHARMACIST DELEGATE** 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) A PRESCRIBER OR PHARMACIST WHO VIOLATES § 21–2A–04.1 ~~OR § 21–2A–04.2~~ OF THIS SUBTITLE SHALL BE SUBJECT TO DISCIPLINARY ACTION BY THE APPROPRIATE LICENSING ENTITY.

[(3)**] (4)** The release of prescription monitoring data by a prescriber **[**or dispenser**], PRESCRIBER DELEGATE, PHARMACIST, OR PHARMACIST DELEGATE** 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.

SECTION 5. AND BE IT FURTHER ENACTED, That the Department of Health and Mental Hygiene shall report, subject to § 2–1246 of the State Government Article, to the Senate Finance Committee, the House Health and Government Operations Committee, and the Joint Committee on Behavioral Health and Opioid Use Disorders, regarding the ongoing implementation and use of the Prescription Drug Monitoring Program, including:

(1) on or before December 1, 2016:

(i) the technical capacity of the Program to analyze prescription drug monitoring data for possible violations of law and possible breaches of professional standards by a prescriber or a dispenser; and

(ii) an analysis of the possibility of reporting possible violations of law or possible breaches of professional standards by a prescriber or a dispenser to law enforcement agencies, licensing entities, or units of the Department of Health and Mental Hygiene; and

(2) on or before September 1, 2017:

(i) in consultation with the Advisory Board on Prescription Drug Monitoring, the status of the implementation of providing education and notice of a possible violation of law or a possible breach of professional standards to prescribers and dispensers, as authorized under § 21–2A–06(d) of the Health – General Article, as enacted by Section 4 of this Act; and

(ii) a recommendation on whether the authority of the Program to report possible violations of law or possible breaches of professional standards should be expanded to allow reporting to law enforcement agencies, licensing boards, or units of the Department of Health and Mental Hygiene.

SECTION 6. AND BE IT FURTHER ENACTED, That, on or before November 1, 2016, the Department of Health and Mental Hygiene shall report, subject to § 2–1246 of the State Government Article, to the Joint Committee on Behavioral Health and Opioid Use Disorders on the feasibility and desirability of analyzing prescription monitoring data through the regular and ongoing use of statistical and advanced analytical techniques, including outlier detection, cluster analysis, and unsupervised data analysis techniques, for the purpose of:

(1) understanding patterns in pain management care, patient opioid use, and treatment plans;

(2) detecting possible high risk opioid behavior;

(3) improving detection of multiple provider episodes; and

(4) facilitating the sharing of information contained in State health and criminal justice records, as allowed by State and federal law, and available from interstate data sources.

SECTION 7. AND BE IT FURTHER ENACTED, That the Department of Health and Mental Hygiene shall develop and implement a plan to conduct outreach to and education of prescribers and pharmacists about the process for registering with the Prescription Drug Monitoring Program, as required by § 21–2A–04.1 of the Health – General Article, as enacted by Section 2 of this Act.

SECTION 8. AND BE IT FURTHER ENACTED, That:

(a) Section 1 of this Act is contingent on a determination by the Secretary of Health and Mental Hygiene, made in consultation with the Advisory Board on Prescription Drug Monitoring, the Joint Committee on Behavioral Health and Opioid Use Disorders, and stakeholders, that:

(1) the requirement to register with the Prescription Drug Monitoring Program will not adversely affect or delay the issuance of a new or renewal registration by the Department of Health and Mental Hygiene under § 5–304(a) of the Criminal Law Article; and

(2) the process for obtaining a new or renewal registration from the Department of Health and Mental Hygiene under § 5–304(a) of the Criminal Law Article is capable of delivering the registrations in a timely manner.

(b) The Secretary of Health and Mental Hygiene shall notify the Department of Legislative Services and, in accordance with § 2–1246 of the State Government Article, the Senate Finance Committee and the House Health and Government Operations Committee within 5 days after the Secretary determines that the contingencies under subsection (a) of this section have been satisfied.

(c) If the notice required under subsection (b) of this section is not received by the Department of Legislative Services on or before June 30, 2022, Section 1 of this Act shall be null and void without the necessity of further action by the General Assembly.

SECTION 9. AND BE IT FURTHER ENACTED, That:

(a) Section 3 of this Act is contingent on a determination by the Secretary of Health and Mental Hygiene, made in consultation with the Advisory Board on Prescription Drug Monitoring, the Joint Committee on Behavioral Health and Opioid Use Disorders, and stakeholders, that:

(1) the technical capabilities of the Prescription Drug Monitoring Program are sufficient to achieve a reasonable standard of access and usability by prescribers and pharmacists; and

(2) requiring a prescriber to request prescription monitoring data for a patient in accordance with § 21–2A–04.2 of the Health – General Article, as enacted by Section 3 of this Act, is important to protect public health and promote good patient care.

(b) The Secretary of Health and Mental Hygiene shall notify the Department of Legislative Services and, in accordance with § 2–1246 of the State Government Article, the Senate Finance Committee and the House Health and Government Operations Committee within 5 days after the Secretary determines that the contingencies under subsection (a) of this section have been satisfied.

(c) If the notice required under subsection (b) of this section is not received by the Department of Legislative Services on or before June 30, 2023, Section 3 of this Act shall be null and void without the necessity of further action by the General Assembly.

SECTION ~~2.~~ 10. AND BE IT FURTHER ENACTED, That, subject to Sections 8 and 9 of this Act, this Act shall take effect October 1, 2016.

Approved:

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Governor.

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President of the Senate.

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Speaker of the House of Delegates.