SENATE BILL 382

J1, J2 6lr0137
CF 6lr0170

By: **The President (By Request – Administration) and Senators Bates, Cassilly, Eckardt, Edwards, Hershey, Hough, Jennings, Kelley, Madaleno, Mathias, Muse, Norman, Ready, Reilly, Rosapepe, Salling, Serafini, Simonaire, and Waugh**

Introduced and read first time: January 28, 2016
Assigned to: Finance

A BILL ENTITLED

AN ACT concerning

Prescription Drug Monitoring Program – Revisions

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 pharmacists be registered with the Program by a certain date; 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, to educate pharmacists, prescriber delegates, and pharmacist delegates about the purpose and operation of the Program; 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; authorizing certain licensing entities to adopt regulations that establish standards of practice for the review of prescription monitoring data; 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 comply with certain provisions of this Act; requiring certain prescribers and pharmacists who do not access prescription monitoring data to take certain actions; altering the information that the Advisory Board on Prescription Drug Monitoring must report annually to the Governor and the General Assembly; repealing a provision of law stating that prescription monitoring data may not be

EXPLANATION: **CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.**
[Brackets**]** indicate matter deleted from existing law.

used as the basis for imposing clinical practice standards; 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; 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(d), 21–2A–07(b), 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
Annotated Code of Maryland
(2015 Replacement Volume)

BY repealing
Article – Health – General
Section 21–2A–06(k)
Annotated Code of Maryland
(2015 Replacement Volume)

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.

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 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;**]**

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

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

[(7)**] (6)** Specify the process for the Program's review of prescription monitoring data and reporting of possible misuse or abuse of a monitored prescription drug under § 21–2A–06(c) of this subtitle;

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

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

(C) A LICENSING ENTITY MAY ADOPT REGULATIONS THAT ESTABLISH STANDARDS OF PRACTICE FOR THE REVIEW OF PRESCRIPTION MONITORING DATA UNDER THIS SUBTITLE.

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.

21–2A–04.2.

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

(I) SHALL REQUEST AT LEAST THE PRIOR 6 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 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 BENZODIAZEPINE.

(2) IF A PRESCRIBER DECIDES TO PRESCRIBE OR CONTINUE TO PRESCRIBE AN OPIOID OR 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) 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) FOR THE TREATMENT OF CANCER–RELATED PAIN;

(2) IN A GENERAL HOSPICE CARE PROGRAM AS DEFINED IN § 19–901 OF THIS ARTICLE;

(3) DIAGNOSED WITH A TERMINAL ILLNESS;

(4) RECEIVING TREATMENT IN AN INPATIENT UNIT OF A LICENSED HOSPITAL; OR

(5) WHO RESIDES IN:

(I) AN ASSISTED LIVING FACILITY;

(II) A LONG–TERM CARE FACILITY;

(III) A COMPREHENSIVE CARE FACILITY; OR

(IV) A DEVELOPMENTAL DISABILITY FACILITY.

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

(1) PRESCRIBING OR DISPENSING AN OPIOID OR 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) IF A PRESCRIBER OR PHARMACIST DOES NOT ACCESS PRESCRIPTION MONITORING DATA UNDER SUBSECTION (D)(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 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.

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.

(d) (1) Before the Program discloses information under subsection (b)(3), (4), (5), **[**(7), or (8)**] (6), OR (9)** of this section, 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.

[(k) 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), (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 under § 21–2A–06(c)(2) of this subtitle.

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