SENATE BILL 195

J1 (9lr0782)

ENROLLED BILL

— Finance/Health and Government Operations —

Introduced by **Senators Kelley, Feldman, Ferguson, Guzzone, Hayes, Kramer, Lam, Peters, Pinsky, Rosapepe, Washington, and Young**

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

Public Health – Prescription Drug Monitoring Program – Revisions

FOR the purpose of requiring, instead of authorizing, the Prescription Drug Monitoring Program to review prescription monitoring data for indications of a possible misuse or abuse of a monitored prescription drug; requiring, instead of authorizing, the Program to report the possible misuse or abuse to the prescriber or dispenser of the monitored prescription drug under certain circumstances; requiring the Program to provide education to the prescriber or dispenser of the monitored prescription drug under certain circumstances; requiring, instead of 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 dispenser; requiring, instead of authorizing, the Program to notify the prescriber or dispenser of the possible violation of law or possible breach of professional standards and provide education to the prescriber or dispenser; authorizing the Program, under certain

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.

circumstances, to provide prescription monitoring data to the Office of Controlled Substances Administration for a certain purpose; requiring the Program, under certain circumstances, to provide a certain notification to certain prescribers or dispensers; requiring the Program to take into account certain factors in making a certain determination; ~~prohibiting the obtaining of certain guidance and interpretation from the technical advisory committee from delaying the reporting of a possible violation of law or a possible breach of professional standards to the Office of Controlled Substances Administration under certain circumstances;~~ authorizing the Program to refer a certain violation of law or a certain breach of professional standards to the Office of Controlled Substances Administration for a certain investigation under certain circumstances and under certain conditions; requiring the Office of Controlled Substances Administration, under certain circumstances, to conduct a certain review and to take certain action; altering a certain reporting requirement; specifying the intent of the General Assembly; defining a certain term; making ~~a~~ conforming ~~change~~ changes; and generally relating to the Prescription Drug Monitoring Program.

BY repealing and reenacting, with amendments,
Article – Health – General
Section 21–2A–01, 21–2A–05(f), and ~~21–2A–06(c) and (d)~~ *21–2A–06(b) through (d)*
Annotated Code of Maryland
(2015 Replacement Volume and 2018 Supplement)

BY repealing and reenacting, without amendments,
Article – Health – General
Section 21–2A–02(a), 21–2A–04, 21–2A–06(a) ~~and (b)~~, and 21–2A–07(a) and (b)
Annotated Code of Maryland
(2015 Replacement Volume and 2018 Supplement)

~~BY repealing and reenacting, with amendments,~~
~~Article – Health – General~~
~~Section 21–2A–06(c) and (d)~~
~~Annotated Code of Maryland~~
~~(2015 Replacement Volume and 2018 Supplement)~~

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, 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.

(b) "Board" means the Advisory Board on Prescription Drug Monitoring.

(c) (1) "Dispense" has the meaning stated in § 12–101 of the Health Occupations Article.

(2) "Dispense" does not include:

(i) Directly administering a monitored prescription drug to a patient; or

(ii) Giving out prescription drug samples.

(d) (1) "Dispenser" means a person authorized by law to dispense a monitored prescription drug to a patient or the patient's agent in the State.

(2) "Dispenser" includes a nonresident pharmacy.

(3) "Dispenser" does not include:

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

(ii) An opioid 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) "OFFICE" MEANS THE OFFICE OF CONTROLLED SUBSTANCES ADMINISTRATION IN THE DEPARTMENT.

[(g)**] (H)** "Opioid treatment services program" means a program that:

(1) Is certified in accordance with § 8–401 of this article or licensed by the State under § 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**]** Office **[**of Controlled Substances Administration**]**; 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)**] (I)** "Pharmacist" means an individual who is licensed under Title 12 of the Health Occupations Article to dispense a monitored prescription drug.

[(i)**] (J)** "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.

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

[(k)**] (L)** "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.

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

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

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

[(o)**] (P)** "Registered" means registered with the Program to request or access prescription monitoring data for clinical use.

[(p)**] (Q)** "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.

(a) There is a Prescription Drug Monitoring Program in the Department.

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;

(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;

(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:

(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 possible 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–05.

(f) The Board shall:

(1) Meet not fewer than three times annually;

(2) Make recommendations to the Secretary relating to the design and implementation of the Program, including recommendations relating to:

(i) Regulations;

(ii) Legislation; and

(iii) Sources of funding, including grant funds under the Harold Rogers Prescription Drug Monitoring Program and other sources of federal, private, or State funds;

(3) 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 pharmacists and pharmacist delegates registered with and using the Program;

(iii) The number of disclosures made to federal law enforcement agencies or State or local law enforcement agencies;

(iv) An analysis of the impact of the Program on patient access to pharmaceutical care and on curbing prescription drug diversion in the State; **[**and**]**

(V) 1. THE NUMBER OF PROVIDERS, BY PROVIDER TYPE, WHO RECEIVED OUTREACH AND EDUCATION FROM THE PROGRAM; AND

2. THE NUMBER OF CASES FOR WHICH THE PROVIDERS RECEIVED OUTREACH AND EDUCATION FROM THE PROGRAM;

(VI) 1. THE NUMBER OF CASES THAT WERE IDENTIFIED FOR TECHNICAL ADVISORY COMMITTEE REVIEW BEFORE REFERRAL TO THE OFFICE; AND

2. THE NUMBER OF PROVIDERS, BY PROVIDER TYPE, INVOLVED IN THE CASES;

(VII) 1. THE NUMBER OF CASES THAT WERE REFERRED TO THE OFFICE FOR FURTHER EVALUATION AND THE OUTCOMES OF THE OFFICE EVALUATIONS; AND

2. THE NUMBER OF PROVIDERS, BY PROVIDER TYPE, INVOLVED IN THE CASES; AND

[(v)**] (VIII)** Any recommendations related to modification or continuation of the Program; and

(4) Provide ongoing advice and consultation on the implementation and operation of the Program, including recommendations relating to:

(i) Changes in the Program to reflect advances in technology and best practices in the field of electronic health records and electronic prescription monitoring;

(ii) Changes to statutory requirements; and

(iii) The design and implementation of an ongoing evaluation component of the Program.

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 (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 (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 Office ~~of Controlled Substances Administration~~;

(10) The technical advisory committee established under § 21–2A–07 of this subtitle for the purposes set forth in subsections (c), (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 report**]** **SHALL:**

1. REPORT the possible misuse or abuse to the prescriber or dispenser of the monitored prescription drug**; AND**

2. PROVIDE EDUCATION TO THE PRESCRIBER OR DISPENSER.

(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 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 **AND SUBJECT TO PARAGRAPH (3) OF THIS SUBSECTION**, the Program **[**may**]** **SHALL** review prescription monitoring data for indications of a possible violation of law or a possible breach of professional standards by a prescriber or a dispenser.

(2) **[**Subject to paragraph (3) of this subsection, if**]** **IF** the Program's review indicates a possible violation of law or a possible breach of professional standards by a prescriber or a dispenser, the Program **[**may**]**:

(i) **1. [**Notify**]** **SHALL NOTIFY** the prescriber or dispenser of the possible violation of law or possible breach of professional standards; and

[(ii)**]** **2. [**Provide**]** **SHALL PROVIDE** education to the prescriber or dispenser**; AND**

(II) ~~1.~~ ~~MAY~~ SUBJECT TO PARAGRAPH (4) OF THIS SUBSECTION, MAY PROVIDE PRESCRIPTION MONITORING DATA TO THE OFFICE ~~OF CONTROLLED SUBSTANCES ADMINISTRATION~~ FOR FURTHER INVESTIGATION~~; AND~~

~~**2. IF PRESCRIPTION MONITORING DATA IS PROVIDED TO THE OFFICE OF CONTROLLED SUBSTANCES ADMINISTRATION UNDER ITEM 1 OF THIS ITEM, SHALL NOTIFY THE PRESCRIBER OR DISPENSER THAT THE DATA HAS BEEN PROVIDED TO THE OFFICE OF CONTROLLED SUBSTANCES ADMINISTRATION FOR FURTHER INVESTIGATION**~~.

(3) **(I)** 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)**]** **1.** Clinical guidance regarding ~~indications of~~ **METHODS USED TO IDENTIFY** a possible violation of law or a possible breach of professional standards; and

[(ii)**]** **2.** Interpretation of the prescription monitoring data **[**that indicates**]** ~~SUFFICIENT TO ADVISE ON~~ ADVISING WHETHER THE METHOD IDENTIFIES a possible violation of law or a possible breach of professional standards.

(II) IN DETERMINING WHETHER ITS REVIEW INDICATES A POSSIBLE VIOLATION OF LAW OR A POSSIBLE BREACH OF PROFESSIONAL STANDARDS BY A PRESCRIBER OR DISPENSER, THE PROGRAM SHALL TAKE INTO ACCOUNT TO THE EXTENT PRACTICABLE THE PARTICULAR SPECIALTY, CIRCUMSTANCES, PATIENT TYPE, AND LOCATION OF THE PRESCRIBER OR DISPENSER.

~~(III) OBTAINING CLINICAL GUIDANCE AND INTERPRETATION OF PRESCRIPTION MONITORING DATA FROM THE TECHNICAL ADVISORY COMMITTEE MAY NOT DELAY REPORTING OF A POSSIBLE VIOLATION OF LAW OR A POSSIBLE BREACH OF PROFESSIONAL STANDARDS TO THE OFFICE OF CONTROLLED SUBSTANCES ADMINISTRATION IF, IN THE JUDGMENT OF THE PROGRAM, A DELAY COULD RESULT IN DANGER TO PUBLIC HEALTH OR PUBLIC SAFETY.~~

(4) (I) IF METHODS DEVELOPED UNDER PARAGRAPH (3)(I) OF THIS SUBSECTION INDICATE A POSSIBLE VIOLATION OF LAW OR A POSSIBLE BREACH OF PROFESSIONAL STANDARDS AND THE PROGRAM DETERMINES THAT OUTREACH AND EDUCATION TO THE PRESCRIBER OR DISPENSER IS INADEQUATE TO ADDRESS THE POSSIBLE BREACH OR VIOLATION, THE PROGRAM MAY REFER THE POSSIBLE VIOLATION OF LAW OR A POSSIBLE BREACH OF PROFESSIONAL STANDARDS ALONG WITH PRESCRIPTION MONITORING DATA TO THE OFFICE FOR FURTHER INVESTIGATION, PROVIDED THAT THE PROGRAM:

1. PROVIDES NOTICE AND AN OPPORTUNITY TO THE TECHNICAL ADVISORY COMMITTEE TO MAKE RECOMMENDATIONS WITHIN 10 BUSINESS DAYS REGARDING INTERPRETATION OF THE DATA;

2. PROVIDES THE RECOMMENDATIONS OF THE TECHNICAL ADVISORY COMMITTEE, IF ANY, TO THE OFFICE; AND

3. NOTIFIES THE PRESCRIBER OR THE DISPENSER THAT THE PRESCRIPTION MONITORING DATA WILL BE PROVIDED TO THE OFFICE FOR FURTHER INVESTIGATION.

~~(4)~~ **(II) ON RECEIPT OF PRESCRIPTION MONITORING DATA AND RELEVANT RECORDS UNDER PARAGRAPH (2) OF THIS SUBSECTION, THE OFFICE** ~~OF CONTROLLED SUBSTANCES ADMINISTRATION~~ **SHALL:**

~~(I)~~ 1. REVIEW THE PRESCRIPTION MONITORING DATA AND RECORDS, ALONG WITH ANY ADDITIONAL INFORMATION THE OFFICE ~~OF CONTROLLED SUBSTANCES ADMINISTRATION~~ MAY OBTAIN AS PART OF ITS INVESTIGATION; AND

~~(II)~~ 2. IF IT DETERMINES THAT THERE HAS BEEN A VIOLATION OF LAW OR A BREACH OF PROFESSIONAL STANDARDS, TAKE ANY ACTION AUTHORIZED BY LAW REGARDING THE VIOLATION OR BREACH, INCLUDING PROVIDING THE PRESCRIPTION MONITORING DATA AND RECORDS TO THE APPROPRIATE LICENSING ENTITY FOR POSSIBLE DISCIPLINARY ACTION.

21–2A–07.

(a) There is a technical advisory committee to the Program.

(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), 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) and (d) of this subtitle.

SECTION 2. AND BE IT FURTHER ENACTED, That it is the intent of the General Assembly that the Prescription Drug Monitoring Program shall continue to work with the Program's technical advisory committee to further refine and enhance the quality of the algorithms and other data tools to identify possible ~~or probable~~ violations of law and breaches of professional standards.

SECTION ~~2.~~ 3. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2019.

Approved:

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Governor.

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President of the Senate.

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Speaker of the House of Delegates.