

SENATE BILL 200

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(PRE-FILED)

By: **Chair, Finance Committee (By Request – Departmental – Health)**

Requested: October 5, 2021

Introduced and read first time: January 12, 2022

Assigned to: Finance

A BILL ENTITLED

1 AN ACT concerning

2 **Public Health – Prescription Drug Monitoring Program – Naloxone Medication**
3 **Data**

4 FOR the purpose of altering the requirements of the Prescription Drug Monitoring Program
5 to require the Program to monitor the dispensing of naloxone medication by all
6 prescribers and dispensers in the State and to require dispensers to report naloxone
7 medication data to the Program; and generally relating to the Prescription Drug
8 Monitoring Program and naloxone medication data.

9 BY repealing and reenacting, with amendments,
10 Article – Health – General
11 Section 21–2A–01 through 21–2A–04, 21–2A–08, and 21–2A–09
12 Annotated Code of Maryland
13 (2019 Replacement Volume and 2021 Supplement)

14 BY adding to
15 Article – Health – General
16 Section 21–2A–06.1
17 Annotated Code of Maryland
18 (2019 Replacement Volume and 2021 Supplement)

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

21 **Article – Health – General**

22 21–2A–01.

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

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 (b) “Board” means the Advisory Board on Prescription Drug Monitoring.

2 (c) (1) “Dispense” has the meaning stated in § 12–101 of the Health
3 Occupations Article.

4 (2) “Dispense” does not include:

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

7 (ii) Giving out prescription drug samples.

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

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

11 (3) “Dispenser” does not include:

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

14 (ii) An opioid treatment services program;

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

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

21 (v) A pharmacy that:

22 1. Dispenses medications to an inpatient hospice; and

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

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

27 (f) **(1)** “Monitored prescription drug” means a prescription drug that contains
28 a Schedule II, Schedule III, Schedule IV, or Schedule V controlled dangerous substance
29 designated under Title 5, Subtitle 4 of the Criminal Law Article.

1 **(2) “MONITORED PRESCRIPTION DRUG” DOES NOT INCLUDE**
2 **NALOXONE MEDICATION.**

3 **(G) “NALOXONE MEDICATION” MEANS AN OPIOID ANTAGONIST APPROVED**
4 **BY THE FEDERAL FOOD AND DRUG ADMINISTRATION FOR THE REVERSAL OF AN**
5 **OPIOID OVERDOSE.**

6 **(H) “NALOXONE MEDICATION DATA” MEANS THE INFORMATION SUBMITTED**
7 **TO THE PROGRAM FOR NALOXONE MEDICATION.**

8 **[(g)] (I)** “Office” means the Office of Controlled Substances Administration in
9 the Department.

10 **[(h)] (J)** “Opioid treatment services program” means a program that:

11 (1) Is certified in accordance with § 8–401 of this article or licensed by the
12 State under § 7.5–401 of this article;

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

15 (3) Complies with:

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

17 (ii) COMAR 10.47.02.11; and

18 (iii) Requirements for the secure storage and accounting of opioid
19 medication imposed by the federal Drug Enforcement Administration and the Office; and

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

23 **[(i)] (K)** “Pharmacist” means an individual who is licensed under Title 12 of the
24 Health Occupations Article, or by another state, to dispense a monitored prescription drug.

25 **[(j)] (L)** “Pharmacist delegate” means an individual who is:

26 (1) Authorized by a registered pharmacist to request or access prescription
27 monitoring data; and

28 (2) Employed by or under contract with the same professional practice as
29 the registered pharmacist.

1 **[(k)] (M)** “Prescriber” means a licensed health care professional authorized by
2 law to prescribe a monitored prescription drug.

3 **[(l)] (N)** “Prescriber delegate” means an individual who is:

4 (1) Authorized by a registered prescriber to request or access prescription
5 monitoring data; and

6 (2) Employed by or under contract with the same professional practice as
7 the prescriber.

8 **[(m)] (O)** “Prescription drug” has the meaning stated in § 21–201 of this title.

9 **[(n)] (P)** “Prescription monitoring data” means the information submitted to the
10 Program for a monitored prescription drug.

11 **[(o)] (Q)** “Program” means the Prescription Drug Monitoring Program
12 established under this subtitle.

13 **[(p)] (R)** “Registered” means registered with the Program to request or access
14 prescription monitoring data for clinical use.

15 **[(q)] (S)** “Terminal illness” means a medical condition that, within reasonable
16 medical judgment, involves a prognosis for a patient that likely will result in the patient’s
17 death within 6 months.

18 21–2A–02.

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

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

21 (1) Assist prescribers, pharmacists, and public health professionals in:

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

23 (ii) The identification and investigation of unlawful prescription
24 drug diversion; and

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

28 (c) To carry out its mission, the Program shall monitor the prescribing and
29 dispensing of all Schedule II, Schedule III, Schedule IV, and Schedule V controlled

1 dangerous substances **AND THE DISPENSING OF NALOXONE MEDICATION** by all
2 prescribers and dispensers in the State.

3 21-2A-03.

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

6 (b) The Secretary may:

7 (1) Assign responsibility for the operation of the Program to any unit in the
8 Department;

9 (2) Contract with any qualified person for the efficient and economical
10 operation of the Program; and

11 (3) Identify and publish a list of monitored prescription drugs that have a
12 low potential for abuse by individuals.

13 (c) Except as provided in subsection (d) of this section, each dispenser shall
14 submit prescription monitoring data **AND NALOXONE MEDICATION DATA** to the Program
15 by electronic means, in accordance with regulations adopted by the Secretary.

16 (d) The Secretary, for good cause shown, may authorize a dispenser to submit
17 prescription monitoring data **OR NALOXONE MEDICATION DATA** by an alternative form
18 of submission.

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

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

23 (2) Educate dispensers, prescribers, pharmacists, prescriber delegates,
24 pharmacist delegates, and consumers about the purpose and operation of the Program.

25 (f) (1) The Secretary shall grant a waiver to a pharmacy that dispenses
26 medications to an inpatient hospice from reporting to the Program prescription monitoring
27 data for hospice inpatients if:

28 (i) The pharmacy demonstrates how it will distinguish hospice
29 inpatients from other consumers receiving medications from the pharmacy; and

30 (ii) The pharmacy agrees that it will be subject to onsite,
31 unannounced inspections by the Department to verify its reporting of the prescription data
32 of consumers who are not hospice inpatients.

1 (2) A waiver granted under this subsection may remain in effect for up to
2 2 years.

3 (3) The Secretary may establish an application process for a pharmacy to
4 apply for a waiver under this subsection.

5 21–2A–04.

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

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

9 (1) Specify the prescription monitoring data **AND NALOXONE**
10 **MEDICATION DATA** required to be submitted under § 21–2A–03 of this subtitle;

11 (2) Specify the electronic or other means by which information is to be
12 submitted:

13 (i) Without unduly increasing the workload and expense on
14 dispensers; and

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

17 (3) Specify that the information be submitted by dispensers once every 24
18 hours;

19 (4) Specify that the Program:

20 (i) Shall provide the information technology software to dispensers
21 necessary to upload prescription drug monitoring data **AND NALOXONE MEDICATION**
22 **DATA** to the Program; and

23 (ii) May not impose any fees or other assessments on prescribers or
24 dispensers to support the operation of the Program;

25 (5) Identify the mechanism by which **[prescription]:**

26 **(I) PRESCRIPTION** monitoring data are disclosed to a person, in
27 accordance with § 21–2A–06 of this subtitle; **AND**

28 **(II) NALOXONE MEDICATION DATA ARE DISCLOSED TO A**
29 **PERSON, IN ACCORDANCE WITH § 21–2A–06.1 OF THIS SUBTITLE;**

1 (6) Identify the circumstances under which a person may disclose
2 prescription monitoring data **OR NALOXONE MEDICATION DATA** received under the
3 Program;

4 (7) Specify the process for the Program's review of prescription monitoring
5 data **AND NALOXONE MEDICATION DATA** and reporting of:

6 (i) Possible misuse or abuse of a monitored prescription drug under
7 § 21-2A-06(c) of this subtitle; or

8 (ii) A possible violation of law or possible breach of professional
9 standards under § 21-2A-06(d) of this subtitle;

10 (8) Establish requirements for Program retention of prescription
11 monitoring data **AND NALOXONE MEDICATION DATA** for 3 years; and

12 (9) Require that:

13 (i) Confidential or privileged patient information be kept
14 confidential; and

15 (ii) Records or information protected by a privilege between a health
16 care provider and a patient, or otherwise required by law to be held confidential, be filed in
17 a manner that, except as otherwise provided in [§ 21-2A-06] **§§ 21-2A-06 AND**
18 **21-2A-06.1** of this subtitle, does not disclose the identity of the person protected.

19 **21-2A-06.1.**

20 (A) **NALOXONE MEDICATION DATA:**

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

24 (2) **ARE NOT PUBLIC RECORDS; AND**

25 (3) **EXCEPT AS PROVIDED IN SUBSECTION (B) OF THIS SECTION OR AS**
26 **OTHERWISE BY LAW, MAY NOT BE DISCLOSED TO ANY PERSON.**

27 (B) (1) **THE PROGRAM SHALL DISCLOSE NALOXONE MEDICATION DATA,**
28 **IN ACCORDANCE WITH REGULATIONS ADOPTED BY THE SECRETARY, FOR PUBLIC**
29 **HEALTH SURVEILLANCE, RESEARCH, ANALYSIS, PUBLIC REPORTING, AND**
30 **EDUCATION AFTER REDACTION OF ALL INFORMATION THAT COULD IDENTIFY A**
31 **PATIENT, PRESCRIBER, DISPENSER, OR ANY OTHER INDIVIDUAL.**

1 **(2) THE SECRETARY MAY REQUIRE SUBMISSION OF AN ABSTRACT**
2 **EXPLAINING THE SCOPE AND PURPOSE OF THE RESEARCH, ANALYSIS, PUBLIC**
3 **REPORTING, OR EDUCATION BEFORE DISCLOSING NALOXONE MEDICATION DATA**
4 **UNDER PARAGRAPH (1) OF THIS SUBSECTION.**

5 21-2A-08.

6 (a) With respect to the administration and operation of the Program, the
7 Department and its agents and employees are not subject to liability arising from:

8 (1) The inaccuracy of any information submitted to the Program in
9 accordance with this subtitle; or

10 (2) The unauthorized use or disclosure of prescription monitoring data **OR**
11 **NALOXONE MEDICATION DATA** by a person to whom the Program was authorized to
12 provide prescription monitoring data **OR NALOXONE MEDICATION DATA** under this
13 subtitle.

14 (b) Except as provided in § 21-2A-09(b)(3) of this subtitle, a prescriber, prescriber
15 delegate, pharmacist, or pharmacist delegate, acting in good faith, is not subject to liability
16 or disciplinary action arising solely from:

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

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

21 21-2A-09.

22 (a) A dispenser who knowingly fails to submit prescription monitoring data **OR**
23 **NALOXONE MEDICATION DATA** to the Program as required under this subtitle shall be
24 subject to a civil penalty not exceeding \$500 for each failure to submit required information.

25 (b) (1) A person who knowingly discloses, uses, obtains, or attempts to obtain
26 by fraud or deceit, prescription monitoring data **OR NALOXONE MEDICATION DATA** in
27 violation of this subtitle shall be guilty of a misdemeanor and on conviction is subject to
28 imprisonment not exceeding 1 year or a fine not exceeding \$10,000 or both.

29 (2) In addition to the penalties under paragraph (1) of this subsection, a
30 prescriber, prescriber delegate, pharmacist, or pharmacist delegate who knowingly
31 discloses or uses prescription monitoring data **OR NALOXONE MEDICATION DATA** in
32 violation of this subtitle shall be subject to disciplinary action by the appropriate licensing
33 entity.

1 (3) A prescriber or pharmacist who violates § 21–2A–04.1 or § 21–2A–04.2
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, prescriber
4 delegate, pharmacist, or pharmacist delegate to a licensed health care professional solely
5 for treatment purposes in a manner otherwise consistent with State and federal law is not
6 a violation of this subtitle.

7 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
8 October 1, 2022.