J1 HB 88/18 – HGO

(PRE-FILED)

9lr0468 CF 9lr0782

#### By: Delegates Barron, Hettleman, Korman, and Moon

Requested: September 11, 2018 Introduced and read first time: January 9, 2019 Assigned to: Health and Government Operations

#### A BILL ENTITLED

1 AN ACT concerning

## 2 Public Health – Prescription Drug Monitoring Program – Revisions

3 FOR the purpose of requiring, instead of authorizing, the Prescription Drug Monitoring 4 Program to review prescription monitoring data for indications of a possible misuse  $\mathbf{5}$ or abuse of a monitored prescription drug; requiring, instead of authorizing, the 6 Program to report the possible misuse or abuse to the prescriber or dispenser of the 7 monitored prescription drug under certain circumstances; requiring the Program to provide education to the prescriber or dispenser of the monitored prescription drug 8 9 under certain circumstances; requiring, instead of authorizing, the Program to 10 review prescription monitoring data for indications of a possible violation of law or a 11 possible breach of professional standards by a prescriber or a dispenser; requiring, 12instead of authorizing, the Program to notify the prescriber or dispenser of the 13 possible violation of law or possible breach of professional standards and provide 14 education to the prescriber or dispenser; authorizing the Program, under certain 15circumstances, to provide prescription monitoring data to the Office of Controlled 16Substances Administration for a certain purpose; requiring the Program, under 17certain circumstances, to provide a certain notification to certain prescribers or 18 dispensers; requiring the Program to take into account certain factors in making a 19certain determination; prohibiting the obtaining of certain guidance and 20interpretation from the technical advisory committee from delaying the reporting of 21a possible violation of law or a possible breach of professional standards to the Office 22of Controlled Substances Administration under certain circumstances; requiring the 23Office of Controlled Substances Administration, under certain circumstances, to 24conduct a certain review and to take certain action; making a conforming change; 25and generally relating to the Prescription Drug Monitoring Program.

26 BY repealing and reenacting, without amendments,

- 27 Article Health General
- 28 Section 21–2A–02(a), 21–2A–04, 21–2A–06(a) and (b), and 21–2A–07(a) and (b)
- 29 Annotated Code of Maryland

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



	2	HOUSE BILL 25
1	(2015	5 Replacement Volume and 2018 Supplement)
$2 \\ 3 \\ 4 \\ 5 \\ 6$	Artic Secti Anno	ng and reenacting, with amendments, le – Health – General on 21–2A–06(c) and (d) otated Code of Maryland 5 Replacement Volume and 2018 Supplement)
7 8		FION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, aws of Maryland read as follows:
9		Article – Health – General
10	21–2A–02.	
11	(a)	There is a Prescription Drug Monitoring Program in the Department.
12	21–2A–04.	
$\begin{array}{c} 13\\14 \end{array}$	(a) out this sub	The Secretary, in consultation with the Board, shall adopt regulations to carry otitle.
15	(b)	The regulations adopted by the Secretary shall:
$\begin{array}{c} 16 \\ 17 \end{array}$	under § 21–	(1) Specify the prescription monitoring data required to be submitted -2A-03 of this subtitle;
$\frac{18}{19}$	submitted:	(2) Specify the electronic or other means by which information is to be
$\begin{array}{c} 20\\ 21 \end{array}$	dispensers;	(i) Without unduly increasing the workload and expense on and
$\begin{array}{c} 22 \\ 23 \end{array}$	submission	(ii) In a manner as compatible as possible with existing data practices of dispensers;
$\begin{array}{c} 24 \\ 25 \end{array}$	hours;	(3) Specify that the information be submitted by dispensers once every 24
26		(4) Specify that the Program:
$\begin{array}{c} 27 \\ 28 \end{array}$	necessary to	(i) Shall provide the information technology software to dispensers o upload prescription drug monitoring data to the Program; and
$\begin{array}{c} 29\\ 30 \end{array}$	dispensers	(ii) May not impose any fees or other assessments on prescribers or to support the operation of the Program;

$\frac{1}{2}$	(5) Identify the mechanism by which prescription monitoring data are disclosed to a person, in accordance with § $21-2A-06$ of this subtitle;
$\frac{3}{4}$	(6) Identify the circumstances under which a person may disclose prescription monitoring data received under the Program;
$5\\6$	(7) Specify the process for the Program's review of prescription monitoring data and reporting of:
$7 \\ 8$	(i) Possible misuse or abuse of a monitored prescription drug under § 21–2A–06(c) of this subtitle; or
9 10	(ii) A possible violation of law or possible breach of professional standards under § 21–2A–06(d) of this subtitle;
$\begin{array}{c} 11 \\ 12 \end{array}$	(8) Establish requirements for Program retention of prescription monitoring data for 3 years; and
13	(9) Require that:
$\begin{array}{c} 14 \\ 15 \end{array}$	(i) Confidential or privileged patient information be kept confidential; and
16 17 18 19	(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.
20	21–2A–06.
21	(a) Prescription monitoring data:
$\begin{array}{c} 22 \\ 23 \end{array}$	(1) Are confidential and privileged, and not subject to discovery, subpoena, or other means of legal compulsion in civil litigation;
24	(2) Are not public records; and
$\begin{array}{c} 25\\ 26 \end{array}$	(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.
$\begin{array}{c} 27\\ 28 \end{array}$	(b) The Program shall disclose prescription monitoring data, in accordance with regulations adopted by the Secretary, to:
29 30	(1) A prescriber, or a licensed health care practitioner authorized by the prescriber, in connection with the medical care of a patient;
31	(2) A dispenser, or a licensed health care practitioner authorized by the

1	dispenser, in connection with the dispensing of a monitored prescription drug;
$2 \\ 3 \\ 4$	(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;
5 6 7 8	(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;
9 10 11	(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;
$\begin{array}{c} 12\\ 13 \end{array}$	(6) A rehabilitation program under a health occupations board, on issuance of an administrative subpoena;
$\begin{array}{c} 14 \\ 15 \end{array}$	(7) A patient with respect to prescription monitoring data about the patient;
$\begin{array}{c} 16 \\ 17 \end{array}$	(8) Subject to subsection (i) of this section, the authorized administrator of another state's prescription drug monitoring program;
18 19	(9) The following units of the Department, on approval of the Secretary, for the purpose of furthering an existing bona fide individual investigation:
20	(i) The Office of the Chief Medical Examiner;
21	(ii) The Maryland Medical Assistance Program;
22	(iii) The Office of the Inspector General;
23	(iv) The Office of Health Care Quality; and
24	(v) The Office of Controlled Substances Administration;
$\begin{array}{c} 25\\ 26 \end{array}$	(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
$\frac{27}{28}$	(11) The following entities, on approval of the Secretary and for the purpose of furthering an existing bona fide individual case review:
$29 \\ 30 \\ 31$	(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;

$\frac{1}{2}$	<ul><li>(ii) A local drug overdose fatality review team established under §</li><li>5–902 of this article, on request from the chair of the local team;</li></ul>
$\frac{3}{4}$	(iii) The Maternal Mortality Review Program established under § $13{-}1203$ of this article, on request from the Program; and
$5 \\ 6$	(iv) A medical review committee described in § $1-401(b)(3)$ of the Health Occupations Article, on request from the committee.
7	(c) (1) In accordance with regulations adopted by the Secretary:
8 9	(i) The Program [may] SHALL review prescription monitoring data for indications of possible misuse or abuse of a monitored prescription drug; and
$10 \\ 11 \\ 12$	(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:
$\frac{13}{14}$	1. <b>REPORT</b> the possible misuse or abuse to the prescriber or dispenser of the monitored prescription drug; <b>AND</b>
15 $16$	2. PROVIDE EDUCATION TO THE PRESCRIBER OR DISPENSER.
17 18 19	(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:
18	prescription drug to a prescriber or dispenser under this subsection, the Program may
18 19 20	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
18 19 20 21 22	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
<ol> <li>18</li> <li>19</li> <li>20</li> <li>21</li> <li>22</li> <li>23</li> <li>24</li> <li>25</li> <li>26</li> </ol>	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

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

(II) 1. MAY PROVIDE PRESCRIPTION MONITORING DATA TO
 THE OFFICE OF CONTROLLED SUBSTANCES ADMINISTRATION FOR FURTHER
 INVESTIGATION; AND

6 2. IF PRESCRIPTION MONITORING DATA IS PROVIDED 7 TO THE OFFICE OF CONTROLLED SUBSTANCES ADMINISTRATION UNDER ITEM 1 OF 8 THIS ITEM, SHALL NOTIFY THE PRESCRIBER OR DISPENSER THAT THE DATA HAS 9 BEEN PROVIDED TO THE OFFICE OF CONTROLLED SUBSTANCES ADMINISTRATION 10 FOR FURTHER INVESTIGATION.

11 (3) (I) Before the Program provides notification of a possible violation 12 of law or a possible breach of professional standards to a prescriber or a dispenser, the 13 Program shall obtain from the technical advisory committee:

14 [(i)] **1.** Clinical guidance regarding indications of a possible 15 violation of law or a possible breach of professional standards; and

16 [(ii)] 2. Interpretation of the prescription monitoring data [that 17 indicates] SUFFICIENT TO ADVISE ON WHETHER THE METHOD IDENTIFIES a possible 18 violation of law or a possible breach of professional standards.

19 (II) IN DETERMINING WHETHER ITS REVIEW INDICATES A 20 POSSIBLE VIOLATION OF LAW OR A POSSIBLE BREACH OF PROFESSIONAL 21 STANDARDS BY A PRESCRIBER OR DISPENSER, THE PROGRAM SHALL TAKE INTO 22 ACCOUNT THE PARTICULAR SPECIALTY, CIRCUMSTANCES, PATIENT TYPE, AND 23 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.

30(4) ON RECEIPT OF PRESCRIPTION MONITORING DATA AND31RELEVANT RECORDS UNDER PARAGRAPH (2) OF THIS SUBSECTION, THE OFFICE OF32CONTROLLED SUBSTANCES ADMINISTRATION SHALL:

33(I) REVIEW THE PRESCRIPTION MONITORING DATA AND34RECORDS, ALONG WITH ANY ADDITIONAL INFORMATION THE OFFICE OF35CONTROLLED SUBSTANCES ADMINISTRATION MAY OBTAIN AS PART OF ITS

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1 INVESTIGATION; AND

2 (II) IF IT DETERMINES THAT THERE HAS BEEN A VIOLATION OF 3 LAW OR A BREACH OF PROFESSIONAL STANDARDS, TAKE ANY ACTION AUTHORIZED 4 BY LAW REGARDING THE VIOLATION OR BREACH, INCLUDING PROVIDING THE 5 PRESCRIPTION MONITORING DATA AND RECORDS TO THE APPROPRIATE LICENSING 6 ENTITY FOR POSSIBLE DISCIPLINARY ACTION.

7 21–2A–07.

- 8 (a) There is a technical advisory committee to the Program.
- 9 (b) The purpose of the technical advisory committee is to:

10 (1) Review requests for information from the Program under 11 21–2A–06(b)(3), (4), (5), (6), (8), or (9) of this subtitle; and

12 (2) Provide clinical guidance and interpretation to the Program regarding 13 indications of possible misuse or abuse of a monitored prescription drug or a possible 14 violation of law or a possible breach of professional standards by a prescriber or a dispenser 15 under § 21–2A–06(c) and (d) of this subtitle.

16 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect 17 October 1, 2019.