HOUSE BILL 3

J1, J2 Slr0371 (PRE-FILED)

By: Delegate Schulz

Requested: September 4, 2014

Introduced and read first time: January 14, 2015 Assigned to: Health and Government Operations

A BILL ENTITLED

-	A TAT	ACIT	•
1	AN	\mathbf{ACT}	concerning
-			COLLECTIONS

Prescription Drug Monitoring Program – Prescribers and Dispensers – Required Query

4 FOR the purpose of requiring regulations adopted by the Secretary of Health and Mental 5 Hygiene for the Prescription Drug Monitoring Program to require a prescriber and a 6 dispenser to query the Program before prescribing or dispensing a monitored 7 prescription drug to a patient; requiring, except under certain circumstances, a 8 prescriber and a dispenser to query the Program for a certain purpose before 9 prescribing or dispensing a monitored prescription drug to a patient; authorizing a 10 prescriber to authorize a designee to query the Program on the prescriber's behalf 11 under certain circumstances; repealing a certain prohibition against a prescriber or 12 a dispenser being subject to disciplinary action arising solely from certain actions; 13 making a prescriber or a dispenser who violates certain provisions of law relating to a query of the Program subject to certain disciplinary action; making a certain 14 15 technical correction; and generally relating to the Prescription Drug Monitoring 16 Program and required queries by prescribers and dispensers.

- 17 BY repealing and reenacting, without amendments,
- 18 Article Health General
- 19 Section 21–2A–01(a), (d), (e), (f), and (h) through (k)
- 20 Annotated Code of Maryland
- 21 (2009 Replacement Volume and 2014 Supplement)
- 22 BY repealing and reenacting, with amendments,
- 23 Article Health General
- 24 Section 21–2A–04, 21–2A–08(b), and 21–2A–09
- 25 Annotated Code of Maryland
- 26 (2009 Replacement Volume and 2014 Supplement)
- 27 BY adding to

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1 2 3 4	Article – Health – General Section 21–2A–04.1 Annotated Code of Maryland (2009 Replacement Volume and 2014 Supplement)
5 6	SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:
7	Article – Health – General
8	21–2A–01.
9	(a) In this subtitle the following words have the meanings indicated.
10 11	(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.
12	(2) "Dispenser" includes a nonresident pharmacy.
13	(3) "Dispenser" does not include:
14 15	(i) A licensed hospital pharmacy that only dispenses a monitored prescription drug for direct administration to an inpatient of the hospital;
16	(ii) An opioid maintenance program;
17 18 19	(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;
20 21 22	(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
23	(v) A pharmacy that:
24	1. Dispenses medications to an inpatient hospice; and
25 26	2. Has been granted a waiver under § 21–2A–03(f) of this subtitle.
27 28	(e) "Licensing entity" means an entity authorized under the Health Occupations Article to license, regulate, or discipline a prescriber or dispenser.
29	(f) "Monitored prescription drug" means a prescription drug that contains a

Schedule II, Schedule IV, or Schedule V controlled dangerous substance

designated under Title 5, Subtitle 4 of the Criminal Law Article.

- 1 (h) "Prescriber" means a licensed health care professional authorized by law to 2 prescribe a monitored prescription drug.
- 3 (i) "Prescription drug" has the meaning stated in § 21–201 of this title.
- 4 (j) "Prescription monitoring data" means the information submitted to the 5 Program for a monitored prescription drug.
- 6 (k) "Program" means the Prescription Drug Monitoring Program established 7 under this subtitle.
- 8 21–2A–04.
- 9 (a) The Secretary, in consultation with the Board, shall adopt regulations to carry 10 out this subtitle.
- 11 (b) The regulations adopted by the Secretary shall:
- 12 (1) Specify the prescription monitoring data required to be submitted 13 under § 21–2A–03 of this subtitle;
- 14 (2) Specify the electronic or other means by which information is to be 15 submitted:
- 16 (i) Without unduly increasing the workload and expense on 17 dispensers; and
- 18 (ii) In a manner as compatible as possible with existing data 19 submission practices of dispensers;
- 20 (3) Specify that the Program:
- 21 (i) Shall provide the information technology software to dispensers 22 necessary to upload prescription drug monitoring 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 (4) [Specify that a prescriber or dispenser is not required or obligated to access or use prescription monitoring data available under the Program] REQUIRE A PRESCRIBER AND A DISPENSER TO QUERY THE PROGRAM IN ACCORDANCE WITH § 28 21–2A–04.1 OF THIS SUBTITLE BEFORE PRESCRIBING OR DISPENSING A MONITORED PRESCRIPTION DRUG TO A PATIENT;
- 30 (5) Identify the mechanism by which prescription monitoring data are disclosed to a person, in accordance with § 21–2A–06 of this subtitle;

- 1 (6) Identify the circumstances under which a person may disclose 2 prescription monitoring data received under the Program;
- 3 (7) 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;
- 6 (8) Establish requirements for Program retention of prescription 7 monitoring data for 3 years; and
- 8 (9) Require that:
- 9 (i) Confidential or privileged patient information be kept 10 confidential; and
- 11 (ii) Records or information protected by a privilege between a health 12 care provider and a patient, or otherwise required by law to be held confidential, be filed in 13 a manner that, except as otherwise provided in § 21–2A–06 of this subtitle, does not disclose 14 the identity of the person protected.
- 15 **21–2A–04.1.**
- 16 (A) EXCEPT AS PROVIDED IN SUBSECTION (C) OF THIS SECTION, A
 17 PRESCRIBER AND A DISPENSER SHALL QUERY THE PROGRAM, FOR THE PURPOSE
 18 OF REVIEWING THE PATIENT'S PRESCRIPTION MONITORING DATA, BEFORE
 19 PRESCRIBING OR DISPENSING A MONITORED PRESCRIPTION DRUG TO A PATIENT.
- 20 **(B)** A PRESCRIBER MAY AUTHORIZE A DESIGNEE TO QUERY THE PROGRAM 21 ON THE PRESCRIBER'S BEHALF IF:
- 22 (1) THE DESIGNEE IS EMPLOYED BY OR UNDER CONTRACT WITH THE 23 SAME PROFESSIONAL PRACTICE AS THE PRESCRIBER;
- 24 (2) THE PRESCRIBER TAKES REASONABLE STEPS TO ENSURE THAT 25 THE DESIGNEE IS COMPETENT IN THE USE OF THE PROGRAM;
- 26 (3) THE PRESCRIBER REMAINS RESPONSIBLE FOR:
- 27 (I) ENSURING THAT ACCESS TO THE PROGRAM BY THE 28 DESIGNEE IS LIMITED TO PURPOSES AUTHORIZED BY LAW AND OCCURS IN A 29 MANNER THAT PROTECTS THE CONFIDENTIALITY OF THE INFORMATION OBTAINED 30 FROM THE PROGRAM; AND
 - (II) ANY BREACH OF CONFIDENTIALITY; AND

1 2	(4) THE DECISION AS TO WHETHER OR NOT TO PRESCRIBE A MONITORED PRESCRIPTION DRUG FOR A PATIENT:
3	(I) REMAINS WITH THE PRESCRIBER; AND
4 5	(II) IS REASONABLY INFORMED BY THE PRESCRIPTION MONITORING DATA OBTAINED FROM THE PROGRAM.
6 7	(C) A PRESCRIBER OR A DISPENSER IS NOT REQUIRED TO QUERY THE PROGRAM IF:
8	(1) THE PROGRAM IS NOT OPERATIONAL, AS DETERMINED BY THE DEPARTMENT;
10 11	(2) THE PRESCRIBER OR THE DISPENSER IS UNABLE TO ACCESS THE PROGRAM DUE TO A TEMPORARY TECHNOLOGICAL OR ELECTRICAL PROBLEM; OR
12 13 14	(3) QUERYING THE PROGRAM WOULD PREVENT A PATIENT FROM OBTAINING A PRESCRIPTION IN A TIMELY MANNER AND POTENTIALLY HARM THE PATIENT'S HEALTH.
15	21–2A–08.
16 17	(b) A prescriber or dispenser, acting in good faith, is not subject to liability [or disciplinary action] arising solely from:
18 19	(1) Requesting or receiving, or failing to request or receive, prescription monitoring data from the Program; or
20 21	(2) Acting, or failing to act, on the basis of prescription monitoring data provided by the Program.
22	21–2A–09.
23 24 25	(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.
26 27 28	(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

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fine not exceeding \$10,000 or both.

- 1 (2) In addition to the penalties under paragraph (1) of this subsection, a 2 prescriber or dispenser who knowingly discloses or uses prescription monitoring data in 3 violation of this subtitle shall be subject to disciplinary action by the appropriate licensing 4 entity.
- 5 (3) A PRESCRIBER OR A DISPENSER WHO VIOLATES § 21–2A–04.1 OF THIS SUBTITLE SHALL BE SUBJECT TO DISCIPLINARY ACTION BY THE APPROPRIATE LICENSING ENTITY.
- 8 **[**(3)**] (4)** The release of prescription monitoring data by a prescriber or A dispenser 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, 2015.