HB0025/866983/1

BY: Health and Government Operations Committee

AMENDMENTS TO HOUSE BILL 25
(First Reading File Bill)

AMENDMENT NO. 1

On page 1, in the sponsor line, strike "and Moon" and substitute "Moon, Pendergrass, Pena–Melnyk, Bagnall, Bhandari, Carr, Charles, Chisholm, Cullison, Hill, Johnson, Kelly, Kerr, Kipke, Krebs, R. Lewis, Metzgar, Morgan, Rosenberg, Saab, Sample–Hughes, Szeliga, and K. Young"; strike beginning with "prohibiting" in line 19 down through "circumstances;" in line 22 and substitute "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;"; in line 24, after "action;" insert "altering a certain reporting requirement; specifying the intent of the General Assembly; defining a certain term;"; in the same line, strike the second "a"; in the same line, strike "change" and substitute "changes"; and after line 25, insert:

"BY repealing and reenacting, with amendments,
Article - Health - General
Section 21-2A-01, 21-2A-05(f), and 21-2A-06(c) and (d)
Annotated Code of Maryland
(2015 Replacement Volume and 2018 Supplement)".

On page 2, strike in their entirety lines 2 through 6, inclusive.

AMENDMENT NO. 2

On page 2, after line 9, insert:

"21–2A–01.

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

(Over)

(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.".

On page 3, after line 19, insert:

"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.".

On page 4, in line 24, strike "of Controlled Substances Administration".

AMENDMENT NO. 3

On page 6, in line 3, strike "**1.**"; in the same line, strike "**MAY**" and substitute "**SUBJECT TO PARAGRAPH (4) OF THIS SUBSECTION, MAY**"; in line 4, strike "**OF CONTROLLED SUBSTANCES ADMINISTRATION**"; strike beginning with the semicolon

in line 5 down through "**INVESTIGATION**" in line 10; in line 14, strike "indications of" and substitute "**METHODS USED TO IDENTIFY**"; in line 17, strike "**SUFFICIENT TO ADVISE ON**" and substitute "**ADVISING**"; in line 22, after "**ACCOUNT**" insert "**TO THE EXTENT PRACTICABLE**"; strike in their entirety lines 24 through 29, inclusive, and substitute:

"**(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.";

in line 30, strike "**(4)**" and substitute "**(II)**"; in lines 31 and 32, strike "**OF CONTROLLED SUBSTANCES ADMINISTRATION**"; in line 33, strike "**(I)**" and substitute "**1.**"; and in lines 34 and 35, strike "**OF CONTROLLED SUBSTANCES ADMINISTRATION**".

On page 7, in line 2, strike "**(II)**" and substitute "**2.**".

AMENDMENT NO. 4

On page 7, after line 15, insert:

"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 violations of law and breaches of professional standards.";

and in line 16, strike "2." and substitute "3.".