

HB0437/286687/1

BY: Health and Government Operations Committee

AMENDMENTS TO HOUSE BILL 437

(First Reading File Bill)

AMENDMENT NO. 1

On page 1, in the sponsor line, strike “and K. Young” and substitute “K. Young, Angel, Bromwell, Hayes, Kelly, Kipke, Krebs, McDonough, McMillan, Miele, Morgan, Oaks, Pena-Melnyk, Pendergrass, Rose, Saab, and West”; in line 4, strike “and prescribers”; in line 6, strike “or by a certain date, whichever is sooner”; in the same line, after the semicolon insert “requiring that certain prescribers be registered with the Program before obtaining a certain new or renewal registration or by a certain date, whichever is sooner”; in line 14, after “Program;” insert “requiring certain regulations adopted by the Secretary to specify a certain frequency for dispensers to submit certain information”; in the same line, strike “altering” and substitute “repealing”; strike beginning with the second “to” in line 16 down through “Program” in line 18; in line 21, after “or” insert “possible”; in lines 22, 28, and 30, in each instance, strike “and pharmacists”; and in line 31, after “actions;” insert “requiring a pharmacist or pharmacist delegate to request prescription monitoring data before dispensing a monitored prescription drug under certain circumstances and for a certain purpose; providing that a pharmacist shall have the responsibility described in a certain federal regulation; authorizing the Secretary to adopt regulations regarding certain exemptions”.

On pages 1 and 2, strike beginning with “requiring” in line 31 on page 1 down through “requiring” in line 3 on page 2 and substitute “authorizing, instead of requiring, the Program to obtain from a certain technical advisory committee certain guidance and interpretation of certain data; authorizing”.

On page 2, in line 4, after the second “a” insert “possible”; in line 5, strike “pharmacist” and substitute “dispenser”; in the same line, strike “requiring” and substitute “authorizing”; in line 6, strike “information” and substitute “education”; in the same line, after “circumstances;” insert “requiring the Program to obtain certain”.

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guidance and certain interpretation of certain data before providing certain notification of certain possible violations; authorizing the Program, under certain circumstances, to request that a certain technical advisory committee review certain requests and provide certain clinical guidance; requiring the Program, in consultation with the Advisory Board on Prescription Drug Monitoring, to consider certain policies and procedures;; in line 8, after “Assembly;” insert “altering the purpose and membership of a certain technical advisory committee;”; in line 14, after “law;” insert “requiring the Department of Health and Mental Hygiene to report to certain committees, on or before certain dates, regarding the ongoing implementation and use of the Program; requiring the Department to report to certain committees, on or before a certain date, on certain matters, for a certain purpose; requiring the Department to develop and implement a certain plan; making certain provisions of this Act subject to certain contingencies; requiring the Secretary to give certain notice to the Department of Legislative Services and certain committees of the General Assembly within a certain time period after the Secretary makes a determination that certain contingencies have been satisfied; providing that certain provisions of this Act shall be null and void under certain circumstances;”; in line 30, after “21-2A-07(b)” insert “and (c)”; in line 36, strike the second “and”; and in the same line, after “21-2A-04.2” insert “, and 21-2A-04.3”.

AMENDMENT NO. 2

On page 3, in line 11, strike “**OR BY JULY 1, 2017, WHICHEVER IS SOONER**”; and after line 20, insert:

“SECTION 2. AND BE IT FURTHER ENACTED, That the Laws of Maryland read as follows:”.

On page 7, after line 8, insert:

“(3) SPECIFY THAT THE INFORMATION BE SUBMITTED BY DISPENSERS ONCE EVERY 24 HOURS;”;

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in line 9, strike “(3)” and substitute “**(4)**”; strike in their entirety lines 14 through 18, inclusive; and in line 27, after “**OR**” insert “**POSSIBLE**”.

AMENDMENT NO. 3

On page 8, in line 15, after “**TRAINING**” insert “**DEVELOPED BY THE DEPARTMENT**”; strike beginning with “**DEVELOPED**” in line 16 down through “**SUBSTANCES**” in line 19 and substitute “**INCLUDING THE EFFECTIVE USE OF THE PROGRAM**”; after line 19, insert:

SECTION 3. AND BE IT FURTHER ENACTED, That the Laws of Maryland read as follows:

Article – Health – General”;

in line 21, strike “**OR PHARMACIST**”; and in line 22, strike “**12**” and substitute “**4**”.

On page 9, strike in their entirety lines 9 through 27, inclusive; in line 28, strike “**(C)**” and substitute “**(B)**”; in the same line, strike “**OR PHARMACIST**”; and in line 31, strike “**7**” and substitute “**3**”.

On page 10, strike beginning with “**ANOTHER**” in line 1 down through “**CANCER**” in line 2 and substitute “**CANCER-RELATED PAIN**”; strike beginning with “**A**” in line 4 down through “**(II)**” in line 8; in line 8, strike “**AT A**” and substitute “**RECEIVING TREATMENT IN AN INPATIENT UNIT OF A**”; strike beginning with the comma in line 8 down through “**EMPLOYEE**” in line 13; in lines 14 and 18, strike “**(III)**” and “**(IV)**”, respectively, and substitute “**(II)**” and “**(III)**”, respectively; strike beginning with “**AT**” in line 14 down through “**9**” in line 15 and substitute “**IN A GENERAL HOSPICE CARE PROGRAM AS DEFINED IN § 19-901**”; strike beginning with “**AT**” in line 18 down through “**SURGERY**” in line 27 and substitute “**WHO RESIDES IN:**”

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1. AN ASSISTED LIVING FACILITY;
2. A LONG-TERM CARE FACILITY;
3. A COMPREHENSIVE CARE FACILITY; OR
4. A DEVELOPMENTAL DISABILITIES FACILITY”;

in line 28, after “TREAT” insert “OR PREVENT”; and strike beginning with “RESULTING” in line 28 down through “CHILDBIRTH” in line 29 and substitute “FOR A PERIOD OF NOT MORE THAN 14 DAYS FOLLOWING:

(I) A SURGICAL PROCEDURE IN WHICH GENERAL ANESTHESIA WAS USED;

(II) A FRACTURE;

(III) SIGNIFICANT TRAUMA; OR

(IV) CHILDBIRTH”.

On page 11, in lines 1 and 14, strike “(D)” and “(E)”, respectively, and substitute “(C)” and “(D)”, respectively; in lines 1, 12, 14, and 17, in each instance, strike “OR PHARMACIST”; in line 13, strike “, AS DESCRIBED IN REGULATION”; in line 16, strike “(D)(2)” and substitute “(C)(2)”; and after line 22, insert:

“(E) IF A PHARMACIST OR PHARMACIST DELEGATE HAS A REASONABLE BELIEF THAT A PATIENT MAY BE SEEKING A MONITORED PRESCRIPTION DRUG FOR ANY PURPOSE OTHER THAN THE TREATMENT OF AN EXISTING MEDICAL CONDITION:

(1) BEFORE DISPENSING A MONITORED PRESCRIPTION DRUG TO THE PATIENT, THE PHARMACIST OR PHARMACIST DELEGATE SHALL REQUEST PRESCRIPTION MONITORING DATA TO DETERMINE IF THE PATIENT HAS RECEIVED OTHER PRESCRIPTIONS THAT INDICATE MISUSE, ABUSE, OR DIVERSION OF A MONITORED PRESCRIPTION DRUG; AND

(2) THE PHARMACIST SHALL HAVE THE RESPONSIBILITY DESCRIBED IN 21 C.F.R. § 1306.04.

(F) THE SECRETARY MAY ADOPT REGULATIONS TO PROVIDE ADDITIONAL CLINICAL, TECHNICAL, OR ADMINISTRATIVE EXEMPTIONS BASED ON NEW STANDARDS OF PRACTICE.

SECTION 4. AND BE IT FURTHER ENACTED, That the Laws of Maryland read as follows:

Article – Health – General

21-2A-04.3.

A PRESCRIBER OR PHARMACIST MAY AUTHORIZE A PRESCRIBER DELEGATE OR PHARMACIST DELEGATE TO REQUEST PRESCRIPTION MONITORING DATA ON BEHALF OF THE PRESCRIBER OR PHARMACIST IF:

(1) THE PRESCRIBER OR PHARMACIST TAKES REASONABLE STEPS TO ENSURE THAT THE PRESCRIBER DELEGATE OR PHARMACIST DELEGATE IS COMPETENT IN THE USE OF THE PROGRAM;

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(2) THE PRESCRIBER OR PHARMACIST REMAINS RESPONSIBLE FOR:

(I) ENSURING THAT ACCESS TO THE PROGRAM BY THE PRESCRIBER DELEGATE OR PHARMACIST DELEGATE IS LIMITED TO PURPOSES AUTHORIZED BY LAW;

(II) PROTECTING THE CONFIDENTIALITY OF THE PRESCRIPTION MONITORING DATA; AND

(III) ANY BREACH OF CONFIDENTIALITY BY THE PRESCRIBER DELEGATE OR PHARMACIST DELEGATE; AND

(3) THE DECISION WHETHER TO PRESCRIBE OR DISPENSE A MONITORED PRESCRIPTION DRUG FOR A PATIENT:

(I) REMAINS WITH THE PRESCRIBER OR PHARMACIST; AND

(II) IS REASONABLY INFORMED BY THE PRESCRIPTION MONITORING DATA OBTAINED FROM THE PROGRAM.”.

AMENDMENT NO. 4

On page 13, in line 6, strike “and” and substitute a comma; in the same line, strike the brackets; in the same line, before “(E)” insert “, **AND**”; in lines 19, 22, and 23, in each instance, strike the brackets; in line 19, strike “**SHALL**”; in line 22, strike “**SHALL**”; strike beginning with “**OR**” in line 24 down through “**DRUG**” in line 25; and in line 27, strike “shall” and substitute “**MAY**”.

On page 14, in lines 4 and 9, in each instance, strike “**SHALL**” and substitute “**MAY**”; in line 5, after the second “A” insert “**POSSIBLE**”; in lines 6 and 9, in each

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instance, strike “PHARMACIST” and substitute “DISPENSER”; in line 7, strike “If” and substitute “SUBJECT TO PARAGRAPH (3) OF THIS SUBSECTION, IF”; in line 8, after “OR” insert “A POSSIBLE”; strike beginning with “APPROPRIATE” in line 10 down through “AGENCY” in line 11 and substitute “PRESCRIBER OR DISPENSER OF THE POSSIBLE VIOLATION OF LAW OR POSSIBLE BREACH OF PROFESSIONAL STANDARDS”; strike beginning with “INFORMATION” in line 12 down through “INVESTIGATION” in line 13 and substitute “EDUCATION TO THE PRESCRIBER OR DISPENSER”; after line 13, insert:

“(3) 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) CLINICAL GUIDANCE REGARDING INDICATIONS OF A POSSIBLE VIOLATION OF LAW OR A POSSIBLE BREACH OF PROFESSIONAL STANDARDS; AND

(II) INTERPRETATION OF THE PRESCRIPTION MONITORING DATA THAT INDICATES A POSSIBLE VIOLATION OF LAW OR A POSSIBLE BREACH OF PROFESSIONAL STANDARDS.”;

in line 15, after “(6),” insert “(8).”; in the same line, after “section,” insert “THE PROGRAM MAY REQUEST THAT”; in the same line, strike “shall”; and strike beginning with “Notwithstanding” in line 22 down through “committee” in line 26 and substitute “THE PROGRAM, IN CONSULTATION WITH THE BOARD, SHALL CONSIDER POLICIES AND PROCEDURES FOR DETERMINING THE CIRCUMSTANCES IN WHICH THE REVIEW OF REQUESTS FOR INFORMATION AND THE PROVISION OF CLINICAL GUIDANCE AND INTERPRETATION OF INFORMATION BY THE TECHNICAL

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ADVISORY COMMITTEE UNDER PARAGRAPH (1) OF THIS SUBSECTION IS FEASIBLE AND DESIRABLE".

AMENDMENT NO. 5

On page 15, in line 27, after "(3)," insert "(4)"; in the same line, strike the brackets; in the same line, after "(8)" insert a comma; in the same line, strike "and"; in line 29, after "drug" insert "OR A POSSIBLE VIOLATION OF LAW OR A POSSIBLE BREACH OF PROFESSIONAL STANDARDS BY A PRESCRIBER OR A DISPENSER"; in line 30, strike "21-2A-06(c)(2)" and substitute "21-2A-06(C) AND (D)"; and after line 30, insert:

"(c) The technical advisory committee consists of [the following members.] MEMBERS appointed by the Secretary, INCLUDING:

(1) A board certified anesthesiologist licensed and practicing in the State, nominated by the Maryland Society of Anesthesiologists;

(2) A certified addiction medicine specialist licensed and practicing in the State, nominated by the Maryland Society for Addiction Medicine;

(3) A pharmacist licensed and practicing in the State;

(4) A medical professional, licensed and practicing in the State, who is treating cancer patients; [and]

(5) A board certified physician specializing in the treatment of patients with pain, licensed and practicing in the State, nominated by the Maryland Society of Physical Medicine and Rehabilitation;

(6) TWO MEDICAL PROFESSIONALS, LICENSED AND PRACTICING IN THE STATE WITH EXPERTISE OR EXPERIENCE IN PROVIDING CARE FOR PATIENTS WITH SUBSTANCE-RELATED OR MENTAL HEALTH DISORDERS;

(7) A DENTIST LICENSED AND PRACTICING IN THE STATE; AND

(8) A MEDICAL PROFESSIONAL LICENSED AND PRACTICING IN THE STATE IN THE FIELD OF INTERNAL MEDICINE OR FAMILY PRACTICE.”

AMENDMENT NO. 6

On page 16, after line 27, insert:

“SECTION 5. AND BE IT FURTHER ENACTED, That the Department of Health and Mental Hygiene shall report, subject to § 2-1246 of the State Government Article, to the Senate Finance Committee, the House Health and Government Operations Committee, and the Joint Committee on Behavioral Health and Opioid Use Disorders, regarding the ongoing implementation and use of the Prescription Drug Monitoring Program, including:

(1) on or before December 1, 2016:

(i) the technical capacity of the Program to analyze prescription drug monitoring data for possible violations of law and possible breaches of professional standards by a prescriber or a dispenser; and

(ii) an analysis of the possibility of reporting possible violations of law or possible breaches of professional standards by a prescriber or a dispenser to law enforcement agencies, licensing entities, or units of the Department of Health and Mental Hygiene; and

(2) on or before September 1, 2017:

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(i) in consultation with the Advisory Board on Prescription Drug Monitoring, the status of the implementation of providing education and notice of a possible violation of law or a possible breach of professional standards to prescribers and dispensers, as authorized under § 21-2A-06(d) of the Health – General Article, as enacted by Section 4 of this Act; and

(ii) a recommendation on whether the authority of the Program to report possible violations of law or possible breaches of professional standards should be expanded to allow reporting to law enforcement agencies, licensing boards, or units of the Department of Health and Mental Hygiene.

SECTION 6. AND BE IT FURTHER ENACTED, That, on or before November 1, 2016, the Department of Health and Mental Hygiene shall report, subject to § 2-1246 of the State Government Article, to the Joint Committee on Behavioral Health and Opioid Use Disorders on the feasibility and desirability of analyzing prescription monitoring data through the regular and ongoing use of statistical and advanced analytical techniques, including outlier detection, cluster analysis, and unsupervised data analysis techniques, for the purpose of:

(1) understanding patterns in pain management care, patient opioid use, and treatment plans;

(2) detecting possible high risk opioid behavior;

(3) improving detection of multiple provider episodes; and

(4) facilitating the sharing of information contained in State health and criminal justice records, as allowed by State and federal law, and available from interstate data sources.

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SECTION 7. AND BE IT FURTHER ENACTED, That the Department of Health and Mental Hygiene shall develop and implement a plan to conduct outreach to and education of prescribers and pharmacists about the process for registering with the Prescription Drug Monitoring Program, as required by § 21-2A-04.1 of the Health – General Article, as enacted by Section 2 of this Act.

SECTION 8. AND BE IT FURTHER ENACTED, That:

(a) Section 1 of this Act is contingent on a determination by the Secretary of Health and Mental Hygiene, made in consultation with the Advisory Board on Prescription Drug Monitoring, the Joint Committee on Behavioral Health and Opioid Use Disorders, and stakeholders, that:

(1) the requirement to register with the Prescription Drug Monitoring Program will not adversely affect or delay the issuance of a new or renewal registration by the Department of Health and Mental Hygiene under § 5-304(a) of the Criminal Law Article; and

(2) the process for obtaining a new or renewal registration from the Department of Health and Mental Hygiene under § 5-304(a) of the Criminal Law Article is capable of delivering the registrations in a timely manner.

(b) The Secretary of Health and Mental Hygiene shall notify the Department of Legislative Services and, in accordance with § 2-1246 of the State Government Article, the Senate Finance Committee and the House Health and Government Operations Committee within 5 days after the Secretary determines that the contingencies under subsection (a) of this section have been satisfied.

(c) If the notice required under subsection (b) of this section is not received by the Department of Legislative Services on or before June 30, 2022, Section 1 of this Act shall be null and void without the necessity of further action by the General Assembly.

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SECTION 9. AND BE IT FURTHER ENACTED, That:

(a) Section 3 of this Act is contingent on a determination by the Secretary of Health and Mental Hygiene, made in consultation with the Advisory Board on Prescription Drug Monitoring, the Joint Committee on Behavioral Health and Opioid Use Disorders, and stakeholders, that:

(1) the technical capabilities of the Prescription Drug Monitoring Program are sufficient to achieve a reasonable standard of access and usability by prescribers and pharmacists; and

(2) requiring a prescriber to request prescription monitoring data for a patient in accordance with § 21-2A-04.2 of the Health – General Article, as enacted by Section 3 of this Act, is important to protect public health and promote good patient care.

(b) The Secretary of Health and Mental Hygiene shall notify the Department of Legislative Services and, in accordance with § 2-1246 of the State Government Article, the Senate Finance Committee and the House Health and Government Operations Committee within 5 days after the Secretary determines that the contingencies under subsection (a) of this section have been satisfied.

(c) If the notice required under subsection (b) of this section is not received by the Department of Legislative Services on or before June 30, 2023, Section 3 of this Act shall be null and void without the necessity of further action by the General Assembly.”;

in line 28, strike “2.” and substitute “10.”; and in the same line, after “That” insert “, subject to Sections 8 and 9 of this Act.”.