

HB1229/466284/1

BY: Health and Government Operations Committee

AMENDMENTS TO HOUSE BILL 1229
(First Reading File Bill)

AMENDMENT NO. 1

On page 1, in line 13, after “Board;” insert “specifying the terms of the initial appointed members of the Board;”; in line 15, after “data;” insert “establishing a technical advisory committee to the Program; establishing the membership and duties of the technical advisory committee;”; in line 19, after “circumstances;” insert “requiring the technical advisory committee to review certain information and provide certain guidance before the Program discloses information to certain agencies and persons;”; in line 27, after “programs;” insert “prohibiting prescription monitoring data from being used as the basis for imposing clinical practice standards;”; and in line 30, after “Program;” insert “providing that the release of prescription monitoring data in a certain manner is not a violation of the requirements of the Program;”.

On page 2, in line 3, after “date;” insert “requiring the Program to develop a mechanism to allow certain persons to correct erroneous data reported to the Program; requiring the Department and the Board to report to the Governor and certain committees of the General Assembly on or before a certain date on certain matters relating to the Program; declaring the intent of the General Assembly regarding technology used by the Program;”; in line 13, strike “21-2A-09” and substitute “21-2A-10”; in line 37, after “care” insert “and public health”; strike beginning with the second comma in line 37 down through “enforcement” in line 38; and in line 38, strike “, treatment,”.

AMENDMENT NO. 2

On page 4, in line 3, strike “AND”; in line 4, after “PROGRAM” insert “;

(III) A VETERINARIAN LICENSED UNDER TITLE 2, SUBTITLE 3 OF THE AGRICULTURE ARTICLE WHEN PRESCRIBING CONTROLLED

(Over)

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”;

after line 11, insert:

“(G) “OPIOID MAINTENANCE PROGRAM” MEANS A PROGRAM THAT:

(1) IS LICENSED BY THE STATE UNDER § 8-404 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 DIVISION OF DRUG CONTROL; 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.;

and in lines 12, 14, 16, and 18, strike “(G)”, “(H)”, “(I)”, and “(J)”, respectively, and substitute “(H)”, “(I)”, “(J)”, and “(K)”, respectively.

AMENDMENT NO. 3

On page 4, in line 26, strike “, TREATMENT,”.

AMENDMENT NO. 4

On page 5, in line 24, after “WITH” insert “**THE MARYLAND HEALTH CARE COMMISSION AND**”; in line 25, strike “**ESTABLISH A WEB SITE FOR THE PROGRAM**” and substitute “**DETERMINE THE APPROPRIATE TECHNOLOGY TO SUPPORT THE OPERATION OF THE PROGRAM**”; after line 27, insert:

“(F) (1) THE SECRETARY SHALL GRANT A WAIVER TO A PHARMACY THAT DISPENSES MEDICATIONS TO AN INPATIENT HOSPICE FROM REPORTING TO THE PROGRAM PRESCRIPTION MONITORING DATA FOR HOSPICE INPATIENTS IF:

(I) THE PHARMACY DEMONSTRATES HOW IT WILL DISTINGUISH HOSPICE INPATIENTS FROM OTHER CONSUMERS RECEIVING MEDICATIONS FROM THE PHARMACY; AND

(II) THE PHARMACY AGREES THAT IT WILL BE SUBJECT TO ONSITE, UNANNOUNCED INSPECTIONS BY THE DEPARTMENT TO VERIFY ITS REPORTING OF THE PRESCRIPTION DATA OF CONSUMERS WHO ARE NOT HOSPICE INPATIENTS.

(2) A WAIVER GRANTED UNDER THIS SUBSECTION MAY REMAIN IN EFFECT FOR UP TO 2 YEARS.

(3) THE SECRETARY MAY ESTABLISH AN APPLICATION PROCESS FOR A PHARMACY TO APPLY FOR A WAIVER UNDER THIS SUBSECTION.”.

AMENDMENT NO. 5

On page 6, in line 7, strike “AND PRESCRIBERS”; after line 9, insert:

“(3) SPECIFY THAT THE PROGRAM:

(I) SHALL PROVIDE THE INFORMATION TECHNOLOGY SOFTWARE TO DISPENSERS NECESSARY TO UPLOAD PRESCRIPTION DRUG MONITORING DATA TO THE PROGRAM; AND

(II) MAY NOT IMPOSE ANY FEES OR OTHER ASSESSMENTS ON PRESCRIBERS OR DISPENSERS TO SUPPORT THE OPERATION OF THE PROGRAM;”;

in lines 10, 13, and 16, strike “(3)”, “(4)”, and “(5)”, respectively, and substitute “(4)”, “(5)”, and “(6)”, respectively; strike in their entirety lines 19 through 25; and in line 27, after “DATA” insert “FOR 3 YEARS”.

AMENDMENT NO. 6

On page 7, in line 4, strike “§ 21-2A-07” and substitute “§ 21-2A-06”; and strike beginning with “ADVISORY” in line 7 down through “MONITORING” in line 8 and substitute “ADVISORY BOARD ON PRESCRIPTION DRUG MONITORING”.

On pages 7 and 8, strike in their entirety the lines beginning with line 9 on page 7 through line 1 on page 8, inclusive, and substitute:

“(B) THE BOARD SHALL CONSIST OF THE FOLLOWING MEMBERS:

- (1) THE SECRETARY, OR THE SECRETARY’S DESIGNEE;**
- (2) THE PRESIDENT OF THE MARYLAND BOARD OF PHARMACY, OR THE PRESIDENT’S DESIGNEE;**
- (3) THE CHAIR OF THE MARYLAND BOARD OF PHYSICIANS, OR THE CHAIR’S DESIGNEE;**
- (4) THE PRESIDENT OF THE MARYLAND BOARD OF NURSING, OR THE PRESIDENT’S DESIGNEE;**
- (5) THE CHAIRMAN OF THE MARYLAND HEALTH CARE COMMISSION, OR THE CHAIRMAN’S DESIGNEE;**
- (6) FOUR PHYSICIANS AND ONE NURSE PRACTITIONER WITH EXPERTISE IN CLINICAL TREATMENT USING CONTROLLED DANGEROUS**

(Over)

SUBSTANCES, INCLUDING PAIN MANAGEMENT, SUBSTANCE ABUSE, AND BEHAVIORAL DISORDERS, APPOINTED BY THE SECRETARY AFTER CONSULTATION WITH:

(I) FOR THE PHYSICIAN APPOINTMENTS, THE MEDICAL AND CHIRURGICAL FACULTY OF MARYLAND, THE MARYLAND PHYSICAL MEDICINE AND REHABILITATION SOCIETY, THE MARYLAND SOCIETY OF ANESTHESIOLOGISTS, THE MARYLAND-D.C. SOCIETY OF CLINICAL ONCOLOGY, THE HOSPICE AND PALLIATIVE CARE NETWORK OF MARYLAND, AND THE MARYLAND CHAPTER OF THE AMERICAN ACADEMY OF PEDIATRICS; AND

(II) FOR THE NURSE PRACTITIONER APPOINTMENT, THE MARYLAND NURSES ASSOCIATION;

(7) ONE PEDIATRICIAN, APPOINTED BY THE SECRETARY AFTER CONSULTATION WITH THE MARYLAND CHAPTER OF THE AMERICAN ACADEMY OF PEDIATRICS;

(8) THREE PHARMACISTS WHO REPRESENT THE PERSPECTIVE OF INDEPENDENT AND CHAIN PHARMACIES, APPOINTED BY THE SECRETARY AFTER CONSULTATION WITH THE MARYLAND PHARMACISTS ASSOCIATION, THE MARYLAND ASSOCIATION OF CHAIN DRUG STORES, AND ANY OTHER APPROPRIATE ORGANIZATION;

(9) A LOCAL LAW ENFORCEMENT OFFICIAL, APPOINTED BY THE SECRETARY AFTER CONSULTATION WITH THE MARYLAND CHIEFS OF POLICE ASSOCIATION AND THE MARYLAND SHERIFF'S ASSOCIATION;

(10) TWO MARYLAND RESIDENTS WHO REPRESENT THE PERSPECTIVE OF PATIENTS, APPOINTED BY THE SECRETARY.

(C) THE SECRETARY SHALL DESIGNATE THE CHAIR OF THE BOARD.

(D) (1) THE TERM OF A MEMBER APPOINTED BY THE SECRETARY IS 3 YEARS.

(2) THE TERMS OF MEMBERS APPOINTED BY THE SECRETARY ARE STAGGERED AS REQUIRED BY THE TERMS PROVIDED FOR MEMBERS OF THE BOARD ON OCTOBER 1, 2011.

(3) IF A VACANCY OCCURS DURING THE TERM OF AN APPOINTED MEMBER, THE SECRETARY SHALL APPOINT A SUCCESSOR WHO SHALL SERVE UNTIL THE TERM EXPIRES.”.

On page 8, in lines 2 and 8, strike “(D)” and “(E)”, respectively, and substitute “(E)” and “(F)”, respectively.

AMENDMENT NO. 7

On page 9, after line 6, insert:

“(G) THE SECRETARY AND THE BOARD SHALL CONSULT WITH STAKEHOLDERS AND PROFESSIONALS KNOWLEDGEABLE ABOUT PRESCRIPTION DRUG MONITORING PROGRAMS AS APPROPRIATE TO OBTAIN INPUT AND GUIDANCE ABOUT IMPLEMENTATION OF THE PROGRAM.”.

AMENDMENT NO. 8

On page 9, in line 17, after “REGULATIONS” insert “ADOPTED BY THE SECRETARY”; in lines 18 and 20, in each instance, strike “ANY OTHER PERSON” and

substitute "A LICENSED HEALTH CARE PRACTITIONER"; in line 27, after "ENTITY" insert ", 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"; after line 27, insert:

"(5) A REHABILITATION PROGRAM UNDER A HEALTH OCCUPATIONS BOARD, ON ISSUANCE OF AN ADMINISTRATIVE SUBPOENA;";

and in line 28, strike "(5)" and substitute "(6)".

On page 10, in lines 1 and 3, strike "(6)" and "(7)", respectively, and substitute "(7)" and "(8)", respectively; in line 1, strike "AN" and substitute "SUBJECT TO SUBSECTION (G) OF THIS SECTION, THE"; in line 2, strike "OR"; in line 3, strike "A UNIT" and substitute "THE FOLLOWING UNITS"; in the same line, after "DEPARTMENT" insert ", ON APPROVAL OF THE SECRETARY, FOR THE PURPOSE OF FURTHERING AN EXISTING BONA FIDE INDIVIDUAL INVESTIGATION:

(I) THE OFFICE OF THE CHIEF MEDICAL EXAMINER;

(II) THE MARYLAND MEDICAL ASSISTANCE PROGRAM;

(III) THE OFFICE OF THE INSPECTOR GENERAL; AND

(IV) THE OFFICE OF HEALTH CARE QUALITY; OR

(9) THE TECHNICAL ADVISORY COMMITTEE ESTABLISHED UNDER § 21-2A-07 OF THIS SUBTITLE FOR THE PURPOSES SET FORTH IN SUBSECTION (C) OF THIS SECTION.

(C) BEFORE THE PROGRAM DISCLOSES INFORMATION UNDER SUBSECTION (B)(3), (4), (5), (7), OR (8) OF THIS SECTION, THE TECHNICAL ADVISORY COMMITTEE TO THE PROGRAM SHALL:

(1) REVIEW THE REQUESTS FOR INFORMATION;

(2) PROVIDE CLINICAL GUIDANCE AND INTERPRETATION OF THE INFORMATION REQUESTED TO THE SECRETARY TO ASSIST IN THE SECRETARY'S DECISION ON HOW TO RESPOND TO A JUDICIAL SUBPOENA, ADMINISTRATIVE SUBPOENA, OR OTHER REQUEST; AND

(3) PROVIDE CLINICAL GUIDANCE AND INTERPRETATION OF THE INFORMATION REQUESTED TO THE AUTHORIZED RECIPIENT OF THE INFORMATION”;

in lines 4, 7, 20, and 23, strike “(C)”, “(D)”, “(E)”, and “(F)”, respectively, and substitute “(D)”, “(E)”, “(F)”, and “(G)”, respectively; in line 4, after “REGULATIONS” insert “ADOPTED BY THE SECRETARY”; strike beginning with the colon in line 23 down through “PROVIDE” in line 24 and substitute “PROVIDE”; in line 25, strike “, PROVIDED” and substitute “ONLY IF”; in line 28, strike the semicolon and substitute a period; after line 28, insert:

“(H) THE PROGRAM MAY:”;

and in line 29, strike “(2)” and substitute “(1)”.

AMENDMENT NO. 9

On page 11, in line 1, strike “(3)” and substitute “(2)”; in line 5, strike “(G)” and substitute “(I)”; after line 8, insert:

(Over)

“(J) PRESCRIPTION MONITORING DATA MAY NOT BE USED AS THE BASIS FOR IMPOSING CLINICAL PRACTICE STANDARDS.”;

after line 9, insert:

“(A) THERE IS A TECHNICAL ADVISORY COMMITTEE TO THE PROGRAM.

“(B) THE PURPOSE OF THE TECHNICAL ADVISORY COMMITTEE IS TO REVIEW REQUESTS FOR INFORMATION FROM THE PROGRAM UNDER § 21-2A-06(B)(3), (4), (5), (7), AND (8) OF THIS SUBTITLE.

“(C) THE TECHNICAL ADVISORY COMMITTEE CONSISTS OF THE FOLLOWING MEMBERS, APPOINTED BY THE SECRETARY:

(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.

21-2A-08.”;

in line 10, strike “**THE**” and substitute “WITH RESPECT TO THE ADMINISTRATION AND OPERATION OF THE PROGRAM, THE”; in line 15, strike “**PROVIDED TO**” and substitute “BY”; in the same line, after “**PERSON**” insert “TO WHOM THE PROGRAM WAS AUTHORIZED TO PROVIDE THE PRESCRIPTION MONITORING DATA UNDER THIS SUBTITLE”; in line 22, strike “**21-2A-08.**” and substitute “21-2A-09.”; and strike in their entirety lines 27 through 30, inclusive.

On page 12, in line 1, strike “**(C)**” and substitute “**(B)**”; in the same line, strike “**DISCLOSES OR USES**” and substitute “DISCLOSES, USES, OBTAINS, OR ATTEMPTS TO OBTAIN BY FRAUD OR DECEIT,”; after line 10, insert:

“(3) THE RELEASE OF PRESCRIPTION MONITORING DATA BY A PRESCRIBER OR 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.”;

and in line 11, strike “**21-2A-09.**” and substitute “21-2A-10.”.

AMENDMENT NO. 10

On page 12, after line 28, insert:

“SECTION 3. AND BE IT FURTHER ENACTED, That the terms of the initial appointed members of the Advisory Board on Prescription Drug Monitoring established under Section 2 of this Act shall expire as follows:

- (1) four members in 2013;

(Over)

- (2) four members in 2014; and
- (3) three members in 2015.

SECTION 4. AND BE IT FURTHER ENACTED, That the Prescription Drug Monitoring Program established under Section 2 of this Act shall develop a mechanism to allow a patient or the patient's prescriber to correct erroneous data reported to the Program relating to the patient's prescription history.

SECTION 5. AND BE IT FURTHER ENACTED, That, on or before December 1, 2012, the Department and the Advisory Board on Prescription Drug Monitoring established under Section 2 of this Act shall report to the Governor and, in accordance with § 2-1246 of the State Government Article, the Senate Finance Committee and the House Health and Government Operations Committee on:

- (1) the status and funding of the Prescription Drug Monitoring Program established under Section 2 of this Act;
- (2) feedback from stakeholders on the operations of the Program;
- (3) any recommendations from the Department and the Advisory Board to improve the operations of the Program; and
- (4) whether a legislative safe harbor provision is recommended to address any access issues experienced by patients after implementation of the Program.

SECTION 6. AND BE IT FURTHER ENACTED, That it is the intent of the General Assembly that the Secretary of Health and Mental Hygiene, in adopting regulations for the Prescription Drug Monitoring Program established under Section 2 of this Act, shall ensure that the technology used by the Program to report

prescription monitoring data to authorized recipients is not subject to manipulation by the recipient.”;

and in line 29, strike “3.” and substitute “7.”.