

**SB0759/367572/1**

BY: Finance Committee

AMENDMENTS TO SENATE BILL 759  
(First Reading File Bill)

AMENDMENT NO. 1

On page 1, in line 10, after the first “staff” insert “and develop a certain budget and plan to be submitted to the Board for approval”.

On page 2, in line 1, after “Act;” insert “requiring the Board in consultation with the Stakeholder Council to collect and review certain information, make a certain determination, monitor and review certain actions, assess certain information, study certain matters, and adopt certain regulations on or before a certain date; requiring the Board to identify certain states and initiate a certain process on or before a certain date; requiring the Board to verify that a certain state has obtained certain consent of a certain owner before taking certain actions; authorizing only certain Board members and staff to access certain information; requiring that the Board’s certain access, use, or sharing of certain information gives rise to a certain cause of action and results in the immediate termination of a certain memorandum of understanding; requiring that, if the Board willfully shares or discloses certain information for certain purposes, the Board shall provide for certain damages;”; in lines 4 and 6, in each instance, strike “a manufacturer” and substitute “certain entities”; strike beginning with “recommend” in line 13 down through “factors” in line 14 and substitute “recommend a certain strategy”; strike beginning with “requiring” in line 14 down through “date;” in line 15 and substitute “providing for the application of certain provisions of this Act;”; strike beginning with “requiring” in line 16 down through “law;” in line 20 and substitute “providing that certain information and data is considered confidential and proprietary and is not subject to disclosure under certain provisions of law;”; strike beginning with “establishing” in line 22 down through “Audits;” in line 26 and substitute “requiring the Board to determine a certain funding source and submit a certain recommendation to certain committees of the General Assembly on or before a certain date;”; and strike beginning with “requiring” in line 29 down through “date;” in line 31 and substitute

(Over)

“requiring the State Designated Health Information Exchange Board jointly to conduct a study with the Board on providing certain data and report certain findings and recommendations to the General Assembly on or before a certain date;”; and in line 36, strike “21-2C-11” and substitute “21-2C-13”.

On pages 2 and 3, strike in their entirety the lines beginning with line 40 on page 2 through line 10 on page 3, inclusive.

AMENDMENT NO. 2

On page 6, after line 18, insert:

**“(3) AT LEAST ONE MEMBER OF THE BOARD SHALL HAVE EXPERTISE IN:**

**(I) THE 340B PROGRAM UNDER THE FEDERAL PUBLIC HEALTH SERVICE ACT;**

**(II) THE STATE’S ALL-PAYER MODEL CONTRACT;**

**(III) HOW THE PROGRAM AND CONTRACT INTERACT; AND**

**(IV) HOW DECISIONS MADE BY THE BOARD WILL AFFECT THE MODEL AND CONTRACT.”;**

in lines 19, 22, and 28, strike “**(3)**”, “**(4)**”, and “**(5)**”, respectively, and substitute “**(4)**”, “**(5)**”, and “**(6)**”, respectively; in line 21, after “**MANUFACTURERS**” insert “**, OR A PHARMACY BENEFITS MANAGER OR A TRADE ASSOCIATION FOR PHARMACY BENEFITS MANAGERS**”.

On page 7, after line 5, insert:

**“(2) THE CHAIR SHALL DEVELOP A 5-YEAR BUDGET AND STAFFING PLAN AND SUBMIT IT TO THE BOARD FOR APPROVAL.”;**

in line 6, strike “(2)” and substitute “(3)”; in line 21, strike “§ 21-2C-07(D)” and substitute “§ 21-2C-08(D)”; in line 22, after “SUBTITLE;” insert “AND”; strike in their entirety lines 23 through 25, inclusive; and in line 26, strike “3.” and substitute “2.”.

On page 9, in line 25, strike “EXCHANGE” and substitute “BOARD”.

AMENDMENT NO. 3

On page 10, in line 6, strike “21” and substitute “26”; after line 8, insert:

**“(I) ONE REPRESENTATIVE OF GENERIC DRUG CORPORATIONS;”**

**“(II) ONE REPRESENTATIVE OF NONPROFIT INSURANCE CARRIERS;”**

in lines 9, 11, 13, 15, 16, and 18, strike “(I)”, “(II)”, “(III)”, “(IV)”, “(V)”, and “(VI)”, respectively, and substitute “(III)”, “(IV)”, “(V)”, “(VI)”, “(VII)”, and “(VIII)”, respectively; in line 16, strike “TWO” and substitute “ONE”; in the same line, strike “RESEARCHERS” and substitute “RESEARCHER”; after line 20, insert:

**“(I) ONE REPRESENTATIVE OF BRAND NAME DRUG CORPORATIONS;”**

in lines 21, 22, and 23, strike “(I)”, “(II)”, and “(III)”, respectively, and substitute “(II)”, “(III)”, and “(IV)”, respectively; in line 21, strike “DOCTORS” and substitute “PHYSICIANS”; after line 23, insert:

(Over)

**“(V) ONE REPRESENTATIVE OF DENTISTS;”**;

in lines 24, 25, and 27, strike “(IV)”, “(V)”, and “(VI)”, respectively, and substitute “(VI)”, “(VII)”, and “(VIII)”, respectively; and in line 24, strike “HEALTH INSURERS” and substitute “MANAGED CARE ORGANIZATIONS”.

On page 11, in line 1, strike “(VII)” and substitute “(IX)”; after line 6, insert:

**“(III) ONE REPRESENTATIVE OF BIOTECHNOLOGY COMPANIES;”**

**“(IV) ONE REPRESENTATIVE OF FOR PROFIT HEALTH INSURANCE CARRIERS;”**;

in lines 7, 8, 10, 11, and 12, strike “(III)”, “(IV)”, “(V)”, “(VI)”, and “(VII)”, respectively, and substitute “(V)”, “(VI)”, “(VII)”, “(VIII)”, and “(IX)”, respectively; in line 14, strike “THE” and substitute “COLLECTIVELY, THE”; and in line 15, strike “IN ONE OR MORE”.

**AMENDMENT NO. 4**

On page 13, after line 11, insert:

**“(A) ON OR BEFORE DECEMBER 31, 2020, THE BOARD, IN CONSULTATION WITH THE STAKEHOLDER COUNCIL, SHALL:**

**(1) COLLECT AND REVIEW PUBLICLY AVAILABLE INFORMATION REGARDING BRAND AND GENERIC BIOPHARMACEUTICAL MANUFACTURERS, HEALTH INSURERS, PHARMACEUTICAL WHOLESALERS, AND PHARMACY BENEFITS MANAGERS;**

**(2) REVIEW ANY INFORMATION REQUESTED UNDER § 21-2C-08(C)(2)(I) OF THIS SUBTITLE;**

**(3) DETERMINE WHAT ADDITIONAL DATA IS NECESSARY TO CARRY OUT ITS DUTIES UNDER THIS SUBTITLE AND HOW TO ACCESS THE DATA;**

**(4) REVIEW AND ASSESS THE PHARMACEUTICAL DISTRIBUTION AND PAYMENT SYSTEM IN THE STATE;**

**(5) MONITOR AND REVIEW POTENTIAL AND ACTUAL FEDERAL CHANGES TO THE PHARMACEUTICAL DISTRIBUTION AND PAYMENT SYSTEM, INCLUDING PROPOSED FEDERAL REGULATIONS THAT WOULD REDUCE OUT-OF-POCKET SPENDING ON PRESCRIPTION DRUGS;**

**(6) MONITOR AND REVIEW FEDERAL REGULATIONS GOVERNING THE MEDICAID DRUG REBATE PROGRAM TO SUPPORT VOLUNTARY, VALUE-BASED PURCHASING ARRANGEMENTS BETWEEN STATES AND MANUFACTURERS;**

**(7) ASSESS THE IMPACT OF POTENTIAL AND ACTUAL FEDERAL CHANGES TO THE PHARMACEUTICAL DISTRIBUTION AND PAYMENT SYSTEM;**

**(8) MONITOR AND REVIEW THE IMPACT OF STEPS TAKEN BY THE DEPARTMENT, THE MARYLAND INSURANCE ADMINISTRATION, AND OTHER STATE AGENCIES TO INCREASE TRANSPARENCY AND LOWER THE COST OF PRESCRIPTION DRUGS;**

**(9) STUDY DIFFERENT CAUSES OF DRUG SHORTAGES AND HOW DRUG SHORTAGES IMPACT THE COST OF PRESCRIPTION DRUG PRODUCTS;**

(Over)

(10) STUDY WHETHER UPPER PAYMENT LIMITS WOULD BE APPROPRIATE IN ADDRESSING COSTS; AND

(11) STUDY OTHER POLICY PROPOSALS FROM ACROSS THE COUNTRY TO LOWER THE COST OF PRESCRIPTION DRUGS, INCLUDING A REVERSE AUCTION MARKETPLACE.

(B) ON OR BEFORE DECEMBER 31, 2020, THE BOARD SHALL:

(1) IDENTIFY STATES THAT REQUIRE REPORTING ON THE COST OF PRESCRIPTION DRUG PRODUCTS; AND

(2) INITIATE A PROCESS OF ENTERING INTO MEMORANDA OF UNDERSTANDING WITH THE STATES IDENTIFIED UNDER ITEM (1) OF THIS SUBSECTION TO AID IN THE COLLECTION OF TRANSPARENCY DATA FOR PRESCRIPTION DRUG PRODUCTS.

(C) (1) BEFORE OBTAINING OR USING ANY INFORMATION OBTAINED THROUGH A MEMORANDUM OF UNDERSTANDING ENTERED INTO WITH ANOTHER STATE UNDER THIS SUBTITLE, THE BOARD SHALL VERIFY THAT THE STATE PROVIDING THE INFORMATION TO THE BOARD HAS OBTAINED THE EXPRESS CONSENT OF THE OWNER OF ANY TRADE SECRET INFORMATION, CONFIDENTIAL COMMERCIAL OR PROPRIETARY INFORMATION, OR INFORMATION DESIGNATED AS CONFIDENTIAL BY THE OWNER OF THE INFORMATION.

(2) ONLY BOARD MEMBERS AND STAFF MAY ACCESS THE INFORMATION OBTAINED THROUGH A MEMORANDUM OF UNDERSTANDING ENTERED INTO WITH ANOTHER STATE UNDER THIS SUBTITLE.

(3) THE BOARD'S UNAUTHORIZED ACCESS, USE, OR SHARING OF ANY TRADE SECRET INFORMATION, CONFIDENTIAL COMMERCIAL OR PROPRIETARY INFORMATION, OR INFORMATION DESIGNATED AS CONFIDENTIAL BY THE OWNER OF THE INFORMATION IN ACCORDANCE WITH A MEMORANDUM OF UNDERSTANDING SHALL:

(I) GIVE RISE TO A CAUSE OF ACTION, AND BE SUBJECT TO ALL APPLICABLE REMEDIES, INCLUDING CIVIL AND CRIMINAL PENALTIES UNDER ANY APPLICABLE FEDERAL AND STATE TRADE SECRET MISAPPROPRIATION LAW; AND

(II) RESULT IN THE IMMEDIATE TERMINATION OF THE MEMORANDUM OF UNDERSTANDING.

(4) IF THE BOARD WILLFULLY SHARES OR DISCLOSES FOR UNAUTHORIZED PURPOSES INFORMATION THAT IS TRADE SECRET INFORMATION, CONFIDENTIAL COMMERCIAL OR PROPRIETARY INFORMATION, OR INFORMATION DESIGNATED AS CONFIDENTIAL BY THE OWNER OF THE INFORMATION, THE BOARD SHALL PROVIDE FOR STATUTORY DAMAGES TO THE OWNER OF THE INFORMATION THE AMOUNT OF \$200,000 PER VIOLATION, IN ADDITION TO BEING SUBJECT TO ANY PENALTIES AVAILABLE UNDER FEDERAL AND STATE LAWS, INCLUDING TRADE SECRET MISAPPROPRIATION LAWS, TO THE EXTENT ALLOWED BY LAW.

(D) BASED ON THE DETERMINATIONS MADE UNDER SUBSECTION (A) OF THIS SECTION AND THE DATA OBTAINED FROM STATES IDENTIFIED UNDER SUBSECTION (B) OF THIS SECTION, THE BOARD, IN CONSULTATION WITH THE STAKEHOLDER COUNCIL, SHALL ADOPT REGULATIONS TO:

(Over)

**(1) ESTABLISH METHODS FOR COLLECTING DATA NECESSARY TO CARRY OUT ITS DUTIES UNDER THIS SECTION; AND**

**(2) IDENTIFY CIRCUMSTANCES UNDER WHICH THE COST OF A PRESCRIPTION DRUG PRODUCT MAY CREATE OR HAS CREATED AFFORDABILITY CHALLENGES FOR THE STATE HEALTH CARE SYSTEM AND PATIENTS.**

**21-2C-08.**

**AMENDMENT NO. 5**

On page 14, in line 29, strike the third “THE” and substitute “:

**1. THE**”;

and in line 30, after “PRODUCT” insert “;**AND**

**2. AS APPROPRIATE, A PHARMACY BENEFITS MANAGER, HEALTH INSURANCE CARRIER, HEALTH MAINTENANCE ORGANIZATION, OR MANAGED CARE ORGANIZATION WITH RELEVANT INFORMATION ON SETTING THE COST OF A PRESCRIPTION DRUG PRODUCT IN THE STATE**”.

On page 15, in line 5, after “MANUFACTURER” insert “,**PHARMACY BENEFITS MANAGER, HEALTH INSURANCE CARRIER, HEALTH MAINTENANCE ORGANIZATION, OR MANAGED CARE ORGANIZATION**”; strike beginning with “OR” in line 8 down through “SECTION” in line 9; and in line 21, after “COST” insert “**AND ANY OTHER RELEVANT PRESCRIPTION DRUG COST INDEX**”.

On page 17, in line 4, after “MANUFACTURER” insert “**AND PHARMACY BENEFITS MANAGER**”; in the same line, after “THE” insert “**PRESCRIPTION DRUG**



PRODUCT UNDER REVIEW FOR THE"; in line 10, strike "(1)"; and strike beginning with "RECOMMEND" in line 12 down through "SUBSECTION" in line 20 and substitute "RECOMMEND A STRATEGY FOR MAKING THE DRUG MORE AFFORDABLE IN THE STATE".

On pages 17 and 18, strike in their entirety the lines beginning with line 21 on page 17 through line 29 on page 18, inclusive, and substitute:

"21-2C-09.

ALL INFORMATION AND DATA COLLECTED BY THE BOARD DURING A REVIEW UNDER THIS SUBTITLE:

(1) IS CONSIDERED TO BE CONFIDENTIAL AND PROPRIETARY INFORMATION; AND

(2) IS NOT SUBJECT TO DISCLOSURE UNDER THE PUBLIC INFORMATION ACT."

AMENDMENT NO. 6

On page 18, in line 30, strike "21-2C-08." and substitute "21-2C-10.".

On page 19, in lines 3 and 11, strike "21-2C-09." and "21-2C-10.", respectively, and substitute "21-2C-11." and "21-2C-12.", respectively; and strike beginning with "THE" in line 6 down through "(C)" in line 8.

On pages 19 and 20, strike in their entirety the lines beginning with line 12 on page 19 through line 12 on page 20, inclusive, and substitute:

(Over)

“(A) (1) ON OR BEFORE DECEMBER 31, 2020, THE BOARD SHALL DETERMINE A FUNDING SOURCE FOR THE BOARD.

(2) IN DETERMINING A FUNDING SOURCE, THE BOARD SHALL CONSIDER:

(I) ASSESSING AND COLLECTING A FEE ON MANUFACTURERS, PHARMACY BENEFIT MANAGERS, HEALTH INSURANCE CARRIERS, OR OTHER ENTITIES;

(II) USING REBATES THE STATE OR LOCAL GOVERNMENT RECEIVES FROM MANUFACTURERS; AND

(III) ANY OTHER METHOD IT DETERMINES APPROPRIATE FOR FUNDING THE BOARD.

(3) ON OR BEFORE DECEMBER 31, 2020, THE BOARD SHALL REPORT BACK TO THE SENATE FINANCE COMMITTEE AND THE HOUSE HEALTH AND GOVERNMENT OPERATIONS COMMITTEE WITH A RECOMMENDATION ON LEGISLATION NECESSARY TO ESTABLISH A FUNDING SOURCE FOR THE BOARD.”.

On page 20, in line 13, strike “(D)” and substitute “(B)”; in lines 14 and 15, strike “ASSESSMENTS REQUIRED UNDER THIS SECTION” and substitute “FUNDS FROM THE FUNDING SOURCE DETERMINED BY THE BOARD UNDER SUBSECTION (A) OF THIS SECTION”; in line 16, strike “21-2C-11.” and substitute “21-2C-13.”; in line 17, after “31” insert “, 2021, AND”; in the same line, strike “YEAR” and substitute “DECEMBER 31 THEREAFTER”; and in line 28, after “STATE” insert “, INCLUDING TO EXPAND THE AUTHORITY OF THE BOARD”.

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On pages 20 and 21, strike in their entirety the lines beginning with line 29 on page 20 through line 12 on page 21, inclusive.

On page 21, in line 22, strike “seven” and substitute “eight”; and in lines 23 and 24, in each instance, strike “seven” and substitute “nine”.

AMENDMENT NO. 7

On page 22, in line 11, strike “Health Services Cost Review Commission” and substitute “Prescription Drug Affordability Board established under § 21–2C–02 of the Health – General Article, as enacted by Section 1 of this Act”; in the same line, after “with” insert “the Prescription Drug Affordability Stakeholder Council established under § 21–2C–04 of the Health – General Article, as enacted by Section 1 of this Act, the Health Services Cost Review Commission, and”; in line 13, strike “upper payment limits and”; in line 18, strike “the upper payment limits established” and substitute “policy actions”; after line 23, insert:

“SECTION 5. AND BE IT FURTHER ENACTED, That, on or before December 1, 2020, the State Designated Health Information Exchange and the Prescription Drug Affordability Board established under § 21–2C–02 of the Health – General Article, as enacted by Section 1 of this Act, jointly shall:

(1) study how the Information Exchange can provide de-identified provider and patient data to the Board; and

(2) report their findings and recommendations, including any necessary statutory changes, to the General Assembly, in accordance with § 2-1246 of the State Government Article.”;

in line 24, strike “5.” and substitute “6.”; in line 29, strike “6.” and substitute “7.”; and in line 30, strike “October” and substitute “July”.