

HB0768/886582/1

BY: Health and Government Operations Committee

AMENDMENTS TO HOUSE BILL 768

(First Reading File Bill)

AMENDMENT NO. 1

On page 1, in the sponsor line, strike “and P. Young” and substitute “P. Young, Pendergrass, Bhandari, and Cullison”; and 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 13, after “Act;” insert “requiring the Board in consultation with the Stakeholder Council to make certain determinations 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;”; in lines 16 and 18, in each instance, strike “a manufacturer” and substitute “certain entities”; in line 25, strike “recommend or establish” and substitute “set”; strike beginning with “requiring” in line 26 down through “date;” in line 27 and substitute “providing for the application of certain provisions of this Act;”; strike beginning with “requiring” in line 28 down through “date;” in line 29; in line 30, strike “establish” and substitute “set”; in the same line, after “limits” insert “for certain prescription drug products”; strike beginning with “requiring” in line 30 down through “law;” in line 32 and substitute “requiring the Board to monitor the availability of certain prescription drug products and reconsider upper payment limits under certain circumstances; prohibiting upper payment limits from applying to a prescription drug product while the prescription drug product is on a certain federal list; 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 34 down through “Audits;” in line 38 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 41 down through “date;” in line 43 and substitute “requiring the

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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;”.

On page 3, in line 2, strike “21-2C-11” and substitute “21-2C-14”; and strike in their entirety lines 6 through 20, inclusive.

AMENDMENT NO. 2

On page 6, after line 25, 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.”;

and in lines 26 and 29, strike “(3)” and “(4)”, respectively, and substitute “(4)” and “(5)”, respectively.

On page 7, in line 5, strike “(5)” and substitute “(6)”; after line 13, insert:

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

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in line 14, strike “(2)” and substitute “(3)”; and in line 29, strike “§ 21-2C-07(D)” and substitute “§ 21-2C-08(D)”.

On page 9, in line 32, strike “EXCHANGE” and substitute “BOARD”.

AMENDMENT NO. 3

On page 10, in line 11, strike “21” and substitute “25”; after line 13, insert:

“(I) ONE REPRESENTATIVE OF GENERIC DRUG CORPORATIONS;

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

in lines 14, 16, 18, 20, 21, and 23, strike “(I)”, “(II)”, “(III)”, “(IV)”, “(V)”, and “(VI)”, respectively, and substitute “(III)”, “(IV)”, “(V)”, “(VI)”, “(VII)”, and “(VIII)”, respectively; in line 21, strike “TWO” and substitute “ONE”; in the same line, strike “RESEARCHERS” and substitute “RESEARCHER”; after line 25, insert:

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

in lines 26 and 27, strike “(I)” and “(II)”, respectively, and substitute “(II)” and “(III)”, respectively; and in line 26, strike “DOCTORS” and substitute “PHYSICIANS”.

On page 11, in lines 1, 2, 3, 5, and 6, strike “(III)”, “(IV)”, “(V)”, “(VI)”, and “(VII)”, respectively, and substitute “(IV)”, “(V)”, “(VI)”, “(VII)”, and “(VIII)”, respectively; in line 2, strike “HEALTH INSURERS” and substitute “MANAGED CARE ORGANIZATIONS”; after line 11, insert:

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“(III) ONE REPRESENTATIVE OF BIOTECHNOLOGY COMPANIES;

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

in lines 12, 13, 15, 16, and 17, strike “(III)”, “(IV)”, “(V)”, “(VI)”, and “(VII)”, respectively, and substitute “(V)”, “(VI)”, “(VII)”, “(VIII)”, and “(IX)”, respectively; in line 19, strike “THE” and substitute “COLLECTIVELY, THE”; and in line 20, strike “IN ONE OR MORE”.

AMENDMENT NO. 4

On page 13, after line 16, insert:

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

(1) WHAT DATA IS NECESSARY TO CARRY OUT ITS DUTIES UNDER THIS SUBTITLE AND HOW TO ACCESS THE DATA; AND

(2) (I) HOW DRUG SHORTAGES IMPACT THE COST OF PRESCRIPTION DRUG PRODUCTS;

(II) DIFFERENT CAUSES OF DRUG SHORTAGES; AND

(III) WHETHER UPPER PAYMENT LIMITS WOULD BE APPROPRIATE IN ADDRESSING COSTS IN THE EVENT OF A DRUG SHORTAGE OR WHETHER UPPER PAYMENT LIMITS WOULD EXACERBATE A DRUG SHORTAGE.

(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) 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:

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

(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; AND

(3) ESTABLISH CRITERIA THE BOARD WILL USE TO SET AN UPPER PAYMENT LIMIT FOR A PRESCRIPTION DRUG PRODUCT AFTER CONSIDERING THE FACTORS IDENTIFIED UNDER § 21-2C-08(E) OF THIS SUBTITLE.

21-2C-08.”.

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On page 15, in line 3, strike the third “THE” and substitute “:

1. THE;

in line 4, 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;

in line 12, after “MANUFACTURER” insert “, PHARMACY BENEFITS MANAGER, HEALTH INSURANCE CARRIER, HEALTH MAINTENANCE ORGANIZATION, OR MANAGED CARE ORGANIZATION”; and in line 28, after “COST” insert “AND ANY OTHER RELEVANT PRESCRIPTION DRUG COST INDEX”.

On page 17, in line 12, after “MANUFACTURER” insert “AND PHARMACY BENEFITS MANAGER”; in the same line, after “THE” insert “PRESCRIPTION DRUG PRODUCT UNDER REVIEW FOR THE”; in line 18, strike “(1)”; in lines 23, 24, and 25, strike “(I)”, “(II)”, and “(III)”, respectively, and substitute “(1)”, “(2)”, and “(3)”, respectively; in line 20, strike “RECOMMEND OR ESTABLISH” and substitute “SET”; in line 21, strike “PARAGRAPH (2) OR (3) OF THIS SUBSECTION” and substitute “§ 21-2C-09 OF THIS SUBTITLE”; in line 24, after “CONSUMERS;” insert “AND”; and strike beginning with “; AND” in line 26 down through “SUBSECTION” in line 28.

On pages 17 through 19, strike in their entirety the lines beginning with line 29 on page 17 through line 3 on page 19, inclusive, and substitute:

“21-2C-09.

(A) THE UPPER PAYMENT LIMITS SET UNDER THIS SECTION DO NOT APPLY TO THE MARYLAND MEDICAL ASSISTANCE PROGRAM.

(B) ON OR AFTER JULY 1, 2021, THE BOARD SHALL SET UPPER PAYMENT LIMITS FOR PRESCRIPTION DRUG PRODUCTS THAT ARE:

(1) PURCHASED OR PAID FOR BY A UNIT OF STATE OR LOCAL GOVERNMENT OR AN ORGANIZATION ON BEHALF OF A UNIT OF STATE OR LOCAL GOVERNMENT, INCLUDING:

(i) STATE OR COUNTY CORRECTIONAL FACILITIES;

(ii) STATE HOSPITALS; AND

(iii) HEALTH CLINICS AT STATE INSTITUTIONS OF HIGHER EDUCATION; OR

(2) PAID FOR THROUGH A HEALTH BENEFIT PLAN ON BEHALF OF A UNIT OF STATE OR LOCAL GOVERNMENT, INCLUDING A COUNTY, BICOUNTY, OR MUNICIPAL EMPLOYEE HEALTH BENEFIT PLAN.

(C) THE UPPER PAYMENT LIMITS SET UNDER SUBSECTION (B) OF THIS SECTION SHALL:

(1) BE FOR PRESCRIPTION DRUG PRODUCTS THAT HAVE LED OR WILL LEAD TO AN AFFORDABILITY CHALLENGE; AND

(2) BE SET IN ACCORDANCE WITH THE CRITERIA ESTABLISHED IN REGULATIONS UNDER § 21-2C-07(C)(3) OF THIS SUBTITLE.

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(D) (1) THE BOARD SHALL:

(I) MONITOR THE AVAILABILITY OF ANY PRESCRIPTION DRUG PRODUCT FOR WHICH IT SETS AN UPPER PAYMENT LIMIT; AND

(II) IF THERE BECOMES A SHORTAGE OF THE PRESCRIPTION DRUG PRODUCT IN THE STATE, RECONSIDER WHETHER THE UPPER PAYMENT LIMIT SHOULD BE SUSPENDED OR ALTERED.

(2) AN UPPER PAYMENT LIMIT SET UNDER SUBSECTION (B) OF THIS SECTION MAY NOT BE APPLIED TO A PRESCRIPTION DRUG PRODUCT WHILE THE PRESCRIPTION DRUG PRODUCT IS ON THE FEDERAL FOOD AND DRUG ADMINISTRATION PRESCRIPTION DRUG SHORTAGE LIST.

21-2C-10.

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 19, in lines 4, 7, and 15, strike “**21-2C-08.**”, “**21-2C-09.**”, and “**21-2C-10.**”, respectively, and substitute “**21-2C-11.**”, “**21-2C-12.**”, and “**21-2C-13.**”, respectively.

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On pages 19 and 20, strike in their entirety the lines beginning with line 16 on page 19 through line 18 on page 20, inclusive, and substitute:

“(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 19, strike “(D)” and substitute “(B)”; in lines 20 and 21, 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 22, strike “21-2C-11.” and substitute

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“21-2C-14.”; in line 23, after “**31**” insert “, **2021, AND**”; and in the same line, strike “**YEAR**” and substitute “**DECEMBER 31 THEREAFTER**”.

On page 21, strike in their entirety lines 4 through 17, inclusive; in lines 27 and 28, in each instance, strike “seven” and substitute “eight”; and line 29, strike “seven” and substitute “nine”.

On page 22, after line 28, insert:

“SECTION 5. AND BE IT FURTHER ENACTED, That, on or before December 1, 2023, the Prescription Drug Affordability Board established under § 21-2C-02 of the Health – General Article, as enacted by Section 1 of this Act, in consultation with the Prescription Drug Affordability Stakeholder Council established under § 21-2C-04 of the Health – General Article, as enacted by Section 1 of this Act, shall report to the Senate Finance Committee and the House Health and Government Operations Committee, in accordance with § 2-1246 of the State Government Article, on:

(1) the legality, obstacles, and benefits of setting upper payment limits on all purchases and payor reimbursements of prescription drug products in the State; and

(2) recommendations regarding whether the General Assembly should pass legislation to expand the authority of the Board to set upper payment limits to all purchases and payor reimbursements of prescription drug products in the State.”.

AMENDMENT NO. 7

On page 22, in line 16, 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

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1 of this Act, the Health Services Cost Review Commission, and"; before line 29, insert:

"SECTION 6. 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."

and in line 29, strike "5." and substitute "7.".

On page 23, in line 3, strike "6." and substitute "8."; and in line 4, strike "October" and substitute "July".