HB0768/463725/1

BY: Conference Committee

AMENDMENTS TO HOUSE BILL 768
(Third Reading File Bill)

AMENDMENT NO. 1

On page 2, in line 22, strike "make certain determinations and adopt certain regulations" and substitute "conduct a certain study and submit a certain report to certain committees of the General Assembly"; in line 23, after "to" insert "collect and review certain information,"; in the same line, before "and" insert a comma; in line 24, after "date;" insert "requiring the Board, in consultation with the Stakeholder Council, to adopt certain regulations;"; in the same line, after "to" insert "use certain information to"; and strike beginning with "requiring" in line 36 down through "date;" in line 43 and substitute "prohibiting certain materials from being made available to the public; authorizing only certain Board members and staff to access certain information; providing that certain provisions of law regarding trade secrets apply to certain information obtained under certain provisions of this Act; requiring the Board to draft a certain plan of action under certain circumstances; requiring that certain criteria include consideration of certain factors; requiring that a certain process prohibit the application of upper payment limits to certain prescription drug products, and require the Board to monitor certain prescriptions drug products and reconsider or suspend certain upper payment limits; requiring the Board, under certain circumstances, to submit a certain plan to the Legislative Policy Committee of the General Assembly for its approval on or before a certain date; providing that the Committee has a certain number of days to approve a certain plan; requiring the Board to submit a certain plan to the Governor and the Attorney General if the Committee does not approve the plan; providing that the Governor and the Attorney General have a certain number of days to approve a certain plan; prohibiting the Board from setting upper payment limits unless a certain plan receives certain approval; authorizing the Board to set upper payment limits for certain prescription drug products on or after a certain date;".

(Over)

On page 3, in line 2, after "considered" insert "to be a trade secret and"; in line 3, after "proprietary" insert "information"; in line 20, after "terms;" insert "providing for the application of this Act; subjecting certain provisions of this Act to a certain contingency; providing for the termination of certain provisions of this Act under certain circumstances;"; and in line 25, strike "21–2C–14" and substitute "21–2C–15".

AMENDMENT NO. 2

On page 7, in line 19, after "**MANUFACTURER**" insert "**, PHARMACY BENEFITS MANAGER, HEALTH INSURANCE CARRIER, HEALTH MAINTENANCE ORGANIZATION, MANAGED CARE ORGANIZATION, OR WHOLESALE DISTRIBUTOR**"; in the same line, after the second "**OR**" insert "**RELATED**"; and in line 20, strike "**FOR MANUFACTURERS**".

On page 8, in line 17, strike "**TO REVIEW PRESCRIPTION DRUG PRODUCT INFORMATION**"; in line 18, strike "**THE**" and substitute "**AT THE CHAIR'S DISCRETION, THE**"; strike beginning with "**IF**" in line 18 down through "**REVIEW**" in line 19; after line 21, insert:

"**1. THE STUDY REQUIRED UNDER § 21–2C–07;**";

in lines 22, 25, and 28, strike "**1.**", "**2.**", and "**3.**", respectively, and substitute "**2.**", "**3.**", and "**4.**", respectively; and in line 30, after "**DISCUSS**" insert "**TRADE SECRETS OR CONFIDENTIAL AND**".

On page 9, in line 3, after "**(3)**" insert "**(I)**"; and after line 4, insert:

"**(II) MATERIALS CONTAINING TRADE SECRETS OR CONFIDENTIAL AND PROPRIETARY DATA OR INFORMATION THAT IS NOT OTHERWISE AVAILABLE TO THE PUBLIC MAY NOT BE MADE AVAILABLE TO THE PUBLIC.**".

On page 11, in line 4, strike "**25**" and substitute "**26**"; after line 26, insert:

"**(V) ONE REPRESENTATIVE OF DENTISTS;**";

and in line 27, strike "**(V)**" and substitute "**(VI)**".

On page 12, in lines 1, 3, and 4, strike "**(VI)**", "**(VII)**", and "**(VIII)**", respectively, and substitute "**(VII)**", "**(VIII)**", and "**(IX)**", respectively.

On page 14, after line 14, insert:

"**ON OR BEFORE DECEMBER 31, 2020, THE BOARD, IN CONSULTATION WITH THE STAKEHOLDER COUNCIL, SHALL:**

(1) STUDY:

(I) THE ENTIRE PHARMACEUTICAL DISTRIBUTION AND PAYMENT SYSTEM IN THE STATE; AND

(II) POLICY OPTIONS BEING USED IN OTHER STATES AND COUNTRIES TO LOWER THE LIST PRICE OF PHARMACEUTICALS, INCLUDING:

1. SETTING UPPER PAYMENT LIMITS;

2. USING A REVERSE AUCTION MARKETPLACE; AND

3. IMPLEMENTING A BULK PURCHASING PROCESS; AND

(2) REPORT ITS FINDINGS AND RECOMMENDATIONS, INCLUDING FINDINGS FOR EACH OPTION STUDIED UNDER ITEM (1)(II) OF THIS SECTION AND ANY LEGISLATION REQUIRED TO IMPLEMENT THE RECOMMENDATIONS, TO THE SENATE FINANCE COMMITTEE AND THE HOUSE HEALTH AND GOVERNMENT OPERATIONS COMMITTEE IN ACCORDANCE WITH § 2–1246 OF THE STATE GOVERNMENT ARTICLE.

21–2C–08.";

strike beginning with "**ON**" in line 15 down through "**(B)**" in line 25; after line 25, insert:

"**(1) COLLECT AND REVIEW PUBLICLY AVAILABLE INFORMATION REGARDING PRESCRIPTION DRUG PRODUCT MANUFACTURERS, HEALTH INSURANCE CARRIERS, HEALTH MAINTENANCE ORGANIZATIONS, MANAGED CARE ORGANIZATIONS, WHOLESALE DISTRIBUTORS, AND PHARMACY BENEFITS MANAGERS; AND**";

in lines 26 and 28, strike "**(1)**" and "**(2)**", respectively, and substitute "**(2)(I)**" and "**(II)**", respectively; and in line 29, strike "**(1)**" and substitute "**(I)**".

On page 15, in line 1, strike "**SUBSECTION**" and substitute "**ITEM**"; in line 3, strike "**(C)**" and substitute "**(B)**"; strike beginning with "**DETERMINATIONS**" in line 3 down through "**SECTION,**" in line 5 and substitute "**INFORMATION COLLECTED UNDER SUBSECTION (A)(1) OF THIS SECTION AND OBTAINED THROUGH MEMORANDA OF UNDERSTANDING UNDER SUBSECTION (A)(2) OF THIS SECTION,**"; in line 7, after "**COLLECTING**" insert "**ADDITIONAL**"; in line 8, strike "**SECTION;**" and substitute "**SUBTITLE; AND**"; in line 11, strike "**; AND**" and substitute a period; strike lines 12 through 19, inclusive; in line 20, strike "**(B)**" and substitute "**(C)**"; and in the same line, after "**SHALL**" insert "**USE THE INFORMATION COLLECTED UNDER SUBSECTION (A)(1) OF THIS SECTION AND OBTAINED**

THROUGH MEMORANDA OF UNDERSTANDING UNDER SUBSECTION (A)(2) OF THIS SECTION TO".

On page 16, after line 21, insert:

"**21–2C–09.**";

in line 22, strike "**(C)**" and substitute "**(A)**"; in line 23, strike "**SUBSECTION (B) OF THIS SECTION**" and substitute "**§ 21–2C–08 OF THIS SUBTITLE**"; and in lines 24 and 31, in each instance, strike "**(D)**" and substitute "**(B)**".

On page 17, in line 3, after "**A**" insert "**WHOLESALE DISTRIBUTOR,**"; in line 6, strike "**A**" and substitute "**THE**"; in line 14, after "**MANUFACTURER**" insert "**, WHOLESALE DISTRIBUTOR**"; strike beginning with "**OR**" in line 19 down through "**SECTION**" in line 20; in lines 19 and 21, in each instance, strike "**(D)**" and substitute "**(B)**"; and strike beginning with "**SUBSECTION**" in line 29 down through "**SECTION**" in line 30 and substitute "**§ 21–2C–08 OF THIS SUBTITLE**".

On page 19, in line 14, strike "**AND**" and substitute a comma; in line 15, after "**MANAGER**" insert "**, AND WHOLESALE DISTRIBUTOR**"; in line 18, after "**MANUFACTURER**" insert "**AND APPROPRIATE HEALTH INSURANCE CARRIERS, HEALTH MAINTENANCE ORGANIZATIONS, MANAGED CARE ORGANIZATIONS, WHOLESALE DISTRIBUTORS, AND PHARMACY BENEFITS MANAGERS**"; and strike beginning with "**(E)**" in line 21 down through the period in line 32.

On page 21, strike in their entirety lines 7 through 9, inclusive, and substitute:

"**(C) ON OR BEFORE DECEMBER 31, 2020, AND EACH DECEMBER 31 THEREAFTER, THE BOARD SHALL SUBMIT TO THE SENATE FINANCE COMMITTEE AND THE HOUSE HEALTH AND GOVERNMENT OPERATIONS COMMITTEE, IN**

ACCORDANCE WITH § 2–1246 OF THE STATE GOVERNMENT ARTICLE, A REPORT THAT INCLUDES:

(1) PRICE TRENDS FOR PRESCRIPTION DRUG PRODUCTS;

(2) THE NUMBER OF PRESCRIPTION DRUG PRODUCTS THAT WERE SUBJECT TO BOARD REVIEW AND THE RESULTS OF THE REVIEW; AND

(3) ANY RECOMMENDATIONS THE BOARD MAY HAVE ON FURTHER LEGISLATION NEEDED TO MAKE PRESCRIPTION DRUG PRODUCTS MORE AFFORDABLE IN THE STATE.

21–2C–10.

(A) ALL INFORMATION AND DATA OBTAINED BY THE BOARD UNDER THIS SUBTITLE, THAT IS NOT OTHERWISE PUBLICLY AVAILABLE:

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

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

(B) ONLY BOARD MEMBERS AND STAFF MAY ACCESS TRADE SECRETS AND CONFIDENTIAL AND PROPRIETARY DATA AND INFORMATION OBTAINED UNDER THIS SUBTITLE THAT IS NOT OTHERWISE PUBLICLY AVAILABLE.

(C) THE PROVISIONS OF TITLE 11, SUBTITLE 12 OF THE COMMERCIAL LAW ARTICLE SHALL APPLY TO ANY TRADE SECRETS AND CONFIDENTIAL AND

PROPRIETARY DATA AND INFORMATION OBTAINED UNDER THIS SUBTITLE THAT IS NOT OTHERWISE PUBLICLY AVAILABLE.

21–2C–11.

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

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

(1) ASSESSING AND COLLECTING A FEE ON MANUFACTURERS, PHARMACY BENEFITS MANAGERS, HEALTH INSURANCE CARRIERS, WHOLESALE DISTRIBUTORS, OR OTHER ENTITIES;

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

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

(C) ON OR BEFORE DECEMBER 31, 2020, IN ACCORDANCE WITH § 2–1246 OF THE STATE GOVERNMENT ARTICLE, 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.

(D) THE BOARD SHALL BE ESTABLISHED USING GENERAL FUNDS, WHICH SHALL BE REPAID TO THE STATE WITH THE FUNDS FROM THE FUNDING SOURCE DETERMINED BY THE BOARD UNDER SUBSECTION (A) OF THIS SECTION.

21–2C–12.

THE OFFICE OF THE ATTORNEY GENERAL MAY PURSUE ANY AVAILABLE REMEDY UNDER STATE LAW WHEN ENFORCING THIS SUBTITLE.

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

Article – Health – General

21–2C–13.

(A) IF, UNDER § 21–2C–07 OF THIS SUBTITLE, THE BOARD FINDS THAT IT IS IN THE BEST INTEREST OF THE STATE TO ESTABLISH A PROCESS FOR SETTING UPPER PAYMENT LIMITS FOR PRESCRIPTION DRUG PRODUCTS THAT IT DETERMINES HAVE LED OR WILL LEAD TO AN AFFORDABILITY CHALLENGE, THE BOARD, IN CONJUNCTION WITH THE STAKEHOLDER COUNCIL, SHALL DRAFT A PLAN OF ACTION FOR IMPLEMENTING THE PROCESS THAT INCLUDES THE CRITERIA THE BOARD SHALL USE TO SET UPPER PAYMENT LIMITS.

(B) THE CRITERIA FOR SETTING UPPER PAYMENT LIMITS SHALL INCLUDE CONSIDERATION OF:

(1) THE COST OF ADMINISTERING THE PRESCRIPTION DRUG PRODUCT;

(2) THE COST OF DELIVERING THE PRESCRIPTION DRUG PRODUCT TO CONSUMERS; AND

(3) OTHER RELEVANT ADMINISTRATIVE COSTS RELATED TO THE PRESCRIPTION DRUG PRODUCT.

(C) THE PROCESS FOR SETTING UPPER PAYMENT LIMITS SHALL:

(1) PROHIBIT THE APPLICATION OF AN UPPER PAYMENT LIMIT FOR A PRESCRIPTION DRUG PRODUCT THAT IS ON THE FEDERAL FOOD AND DRUG ADMINISTRATION PRESCRIPTION DRUG SHORTAGE LIST; AND

(2) REQUIRE THE BOARD TO:

(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 OR SUSPEND THE UPPER PAYMENT LIMIT.

(D) (1) IF A PLAN OF ACTION IS DRAFTED UNDER SUBSECTION (A) OF THIS SECTION, ON OR BEFORE JULY 1, 2021, THE BOARD SHALL SUBMIT THE PLAN OF ACTION TO THE LEGISLATIVE POLICY COMMITTEE OF THE GENERAL ASSEMBLY, IN ACCORDANCE WITH § 2–1246 OF THE STATE GOVERNMENT ARTICLE, FOR ITS APPROVAL.

(2) THE LEGISLATIVE POLICY COMMITTEE SHALL HAVE 45 DAYS TO APPROVE THE PLAN OF ACTION.

(3) IF THE LEGISLATIVE POLICY COMMITTEE DOES NOT APPROVE THE PLAN OF ACTION, THE BOARD SHALL SUBMIT THE PLAN TO THE GOVERNOR AND THE ATTORNEY GENERAL FOR APPROVAL.

(4) THE GOVERNOR AND THE ATTORNEY GENERAL SHALL HAVE 45 DAYS TO APPROVE THE PLAN OF ACTION.

(5) THE BOARD MAY NOT SET UPPER PAYMENT LIMITS UNLESS THE PLAN IS APPROVED, IN ACCORDANCE WITH THIS SUBSECTION, BY:

(I) THE LEGISLATIVE POLICY COMMITTEE; OR

(II) 1. THE GOVERNOR; AND

2. THE ATTORNEY GENERAL.

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

Article – Health – General

21–2C–13.";

in lines 10, 22, and 28, strike "**(B)**", "**(C)**", and "**(D)**", respectively, and substitute "**(A)**", "**(B)**", and "**(C)**", respectively; in line 10, strike "**JULY 1, 2021**" and substitute "**JANUARY 1, 2022**"; in the same line, strike "**SHALL**" and substitute "**MAY**"; in line 18, strike "**OR**"; in line 21, after "**PLAN**" insert"**; OR**

(3) PURCHASED FOR OR PAID FOR BY THE MARYLAND STATE MEDICAL ASSISTANCE PROGRAM";

in line 22, strike "**(B)**" and substitute "**(A)**"; and strike beginning with the second "**IN**" in line 26 down through "**SUBTITLE**" in line 27 and substitute "**IN REGULATIONS ADOPTED BY THE BOARD**".

On page 22, in line 6, strike "**(B)**" and substitute "**(A)**"; strike in their entirety lines 10 through 19, inclusive; in line 20, strike "**21–2C–12.**" and substitute "**21–2C–14.**"; and in line 28, strike "**21–2C–13.**".

On page 23, strike in their entirety lines 29 and 30.

On page 24, strike in their entirety lines 1 through 31, inclusive, and substitute:

"**21–2C–15.**

ON OR BEFORE DECEMBER 1, 2023, THE BOARD, IN CONSULTATION WITH THE STAKEHOLDER COUNCIL, 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.".

On page 25, in lines 14 and 26, strike "2." and "3.", respectively, and substitute "4." and "5.", respectively; and in line 24, strike "eight" and substitute "nine".

On page 26, in line 11, strike "4." and substitute "6."; in line 18, strike "upper payment limits and"; in line 19, after "actions" insert ", including, if applicable, upper payment limits,"; in line 23, strike "the upper payment limits established" and substitute "policy actions, including, if applicable, upper payment limits,"; and strike lines 29 through 33, inclusive.

On page 27, strike in their entirety lines 1 through 7, inclusive; in line 8, strike "6." and substitute "7."; in line 17, strike "7." and substitute "8."; after line 21, insert:

"SECTION 9. AND BE IT FURTHER ENACTED, That Section 3 of this Act shall take effect contingent on receipt by the Prescription Drug Affordability Board established under § 21–2C–02 of the Health – General Article, as enacted by Section 1 of this Act of approval by the Legislative Policy Committee of the General Assembly or the Governor and the Attorney General of the plan of action for implementing a process for setting upper payment limits in accordance with § 21–2C–13 of the Health – General Article, as enacted by Section 2 of this Act. The Board, within 5 days after receiving approval from the Legislative Policy Committee or the Governor and the Attorney General, shall forward evidence of the approval to the Department of Legislative Services, 90 State Circle, Annapolis, Maryland 21401. If the Board receives approval for the plan of action on or before January 1, 2023, Section 2 of this Act, with no further action required by the General Assembly, shall be abrogated and of no further force and effect and Section 3 of this Act shall take effect on the date evidence of the approval is received by the Department of Legislative Services in accordance with this section. If the Board does not receive approval of the plan of action on or before January 1, 2023, Section 2 of this Act, with no further action required by the General Assembly, shall be abrogated and of no further force and effect and Section 3 of this Act shall be null and void.";

in line 22, strike "8." and substitute "10."; and in the same line, after "That" insert ", subject to Section 9 of this Act,".