SENATE BILL 759

J1, C3 9lr0964
CF 9lr0936

By: **Senators Klausmeier and Lam**
Introduced and read first time: February 4, 2019
Assigned to: Finance

A BILL ENTITLED

AN ACT concerning

Health – Prescription Drug Affordability Board

FOR the purpose of establishing the Prescription Drug Affordability Board as an independent unit of State government; providing that the exercise by the Board of its authority under this Act is an essential governmental function; providing for the purpose of the Board; providing for the membership, terms, compensation, and chair of the Board; requiring certain conflicts of interest to be disclosed and considered when appointing members to the Board; specifying the terms of the initial members and alternate members of the Board; requiring the chair of the Board to hire certain staff; requiring that the staff of the Board receive a certain salary; requiring the Board to meet in a certain manner and with a certain frequency with certain exceptions; requiring the Board to provide certain public notice of each Board meeting and to make certain materials available to the public in a certain manner; requiring the Board to provide the public with the opportunity to provide certain comments; authorizing the Board to allow expert testimony under certain circumstances; requiring the Board to access certain information for prescription drug products in a certain manner; requiring certain actions by the Board to be made in open session; providing that a majority of the members of the Board constitutes a quorum; requiring members of the Board to recuse themselves from certain decisions under certain circumstances; authorizing the Board to adopt certain regulations and enter into certain contracts; providing that certain third parties may not use certain information except under certain circumstances; providing for the application of certain procurement law to the Board; establishing the Prescription Drug Affordability Stakeholder Council; providing for the purpose of the Stakeholder Council; providing for the membership of the Stakeholder Council; specifying the terms of the initial members of the Stakeholder Council; requiring the Board to appoint certain chairs for the Stakeholder Council; prohibiting a member of the Stakeholder Council from receiving certain compensation, but authorizing the reimbursement of certain expenses; requiring the disclosure of certain conflicts of interest within a certain time frame and in a certain manner; prohibiting certain persons from accepting certain gifts or donations; providing for the construction of

EXPLANATION: **CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.**
[Brackets**]** indicate matter deleted from existing law.

certain provisions of this Act; requiring the Board to identify certain prescription drug products with certain costs; requiring the Board to determine in a certain manner whether to conduct a certain review for certain identified products; requiring the Board to request certain information from a manufacturer under certain circumstances; providing that information to conduct a certain cost review includes certain documents and research; providing that failure of a manufacturer to provide the Board with certain information does not affect certain Board authority; requiring that a certain review determine if certain utilization of a prescription drug product has led or will lead to certain challenges; requiring the Board to consider certain factors in making a certain determination on whether a certain drug product has led or will lead to certain challenges; authorizing the Board to consider certain additional factors if the Board is unable to make a certain determination; requiring the Board to recommend or establish certain upper payment limits after considering certain factors; requiring the Board to work with certain stakeholders to identify certain methodologies and establish certain data sources on or before a certain date; requiring the Board to consider certain information and recommend and publicize certain upper payment limits on or before a certain date; requiring the Board to establish certain upper payment limits on or after a certain date; requiring that certain information be subject to public inspection to the extent allowed under certain provisions of law; authorizing the Office of the Attorney General to pursue certain remedies; authorizing certain appeals and judicial review of certain Board decisions; establishing the Prescription Drug Affordability Fund; requiring the Board to be funded by a certain assessment; requiring the Board to assess and collect certain fees; requiring the State Treasurer to hold the Fund separately, and the Comptroller to account for the Fund; providing that the Fund is not subject to certain provisions of law but is subject to certain audit by the Office of Legislative Audits; requiring the Board to be funded in a certain manner; requiring the Board to submit certain reports to certain committees of the General Assembly and to the General Assembly on or before certain dates; requiring the Health Services Cost Review Commission, in consultation with the Maryland Health Care Commission, to submit a certain report to the General Assembly on or before a certain date; defining certain terms; making the provisions of this Act severable; and generally relating to the Prescription Drug Affordability Board.

BY adding to
Article – Health – General
Section 21–2C–01 through 21–2C–11 to be under the new subtitle "Subtitle 2C. Prescription Drug Affordability Board"
Annotated Code of Maryland
(2015 Replacement Volume and 2018 Supplement)

BY repealing and reenacting, without amendments,
Article – State Finance and Procurement
Section 6–226(a)(2)(i)
Annotated Code of Maryland
(2015 Replacement Volume and 2018 Supplement)

BY repealing and reenacting, with amendments,
Article – State Finance and Procurement
Section 6–226(a)(2)(ii)112. and 113.
Annotated Code of Maryland
(2015 Replacement Volume and 2018 Supplement)

BY adding to
Article – State Finance and Procurement
Section 6–226(a)(2)(ii)114.
Annotated Code of Maryland
(2015 Replacement Volume and 2018 Supplement)

Preamble

WHEREAS, Prescription medications are important to the health and safety of Maryland residents; and

WHEREAS, Maryland has achieved success in regulating costs within the health care industry, including through the Health Services Cost Review Commission, which has saved Maryland over $45 billion and ensured continued access to high quality care for Maryland residents; and

WHEREAS, Many prescription drugs have become increasingly unaffordable for Maryland residents, employers, and State and local governments because parts of the prescription drug market exert monopoly and oligopoly pressure, creating unmanageable costs for consumers across wide market segments, leading to a rising, unsustainable strain on State and commercial health plan budgets and lowering equitable access to life–sustaining medications for Maryland residents; and

WHEREAS, Other sectors across widely varying industries, such as research universities, academic and safety net hospitals, public utilities, and telecommunications, often receive public funds and State protections and are regulated routinely to ensure affordability but still maintain their ability to innovate and provide accessible products to many consumers; and

WHEREAS, State and federal agencies have a long history of health care rate setting including for name brand pharmaceuticals, biologics, and generic drugs to manage health care costs; and

WHEREAS, All public and private health care programs, including Medicaid and State employee benefit programs, set payment rates for generic and patient–protected drugs; and

WHEREAS, State Medicaid, State employee health benefit programs, and private health insurers set prescription drug payment rates that drive negotiations and financial transactions through the supply chain, which may be out of State; and

WHEREAS, Maryland taxpayers support the pharmacy benefit for almost one–third of State residents; now, therefore,

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

Article – Health – General

SUBTITLE 2C. PRESCRIPTION DRUG AFFORDABILITY BOARD.

21–2C–01.

(A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS INDICATED.

(B) "BIOLOGIC" MEANS A DRUG THAT IS PRODUCED OR DISTRIBUTED IN ACCORDANCE WITH A BIOLOGICS LICENSE APPLICATION APPROVED UNDER 42 C.F.R. § 447.502.

(C) "BIOSIMILAR" MEANS A DRUG THAT IS PRODUCED OR DISTRIBUTED IN ACCORDANCE WITH A BIOLOGICS LICENSE APPLICATION APPROVED UNDER 42 U.S.C. § 262(K)(3).

(D) "BOARD" MEANS THE PRESCRIPTION DRUG AFFORDABILITY BOARD.

(E) (1) "BRAND NAME DRUG" MEANS A DRUG THAT IS PRODUCED OR DISTRIBUTED IN ACCORDANCE WITH AN ORIGINAL NEW DRUG APPLICATION APPROVED UNDER 21 U.S.C. § 355(C).

(2) "BRAND NAME DRUG" DOES NOT INCLUDE AN AUTHORIZED GENERIC AS DEFINED BY 42 C.F.R. § 447.502.

(F) "GENERIC DRUG" MEANS:

(1) A RETAIL DRUG THAT IS MARKETED OR DISTRIBUTED IN ACCORDANCE WITH AN ABBREVIATED NEW DRUG APPLICATION, APPROVED UNDER 21 U.S.C. § 355(J);

(2) AN AUTHORIZED GENERIC AS DEFINED BY 42 C.F.R. § 447.502; OR

(3) A DRUG THAT ENTERED THE MARKET BEFORE 1962 THAT WAS NOT ORIGINALLY MARKETED UNDER A NEW DRUG APPLICATION.

(G) "MANUFACTURER" MEANS AN ENTITY THAT:

(1) (I) ENGAGES IN THE MANUFACTURE OF A PRESCRIPTION DRUG PRODUCT; OR

(II) ENTERS INTO A LEASE WITH ANOTHER MANUFACTURER TO MARKET AND DISTRIBUTE A PRESCRIPTION DRUG PRODUCT UNDER THE ENTITY'S OWN NAME; AND

(2) SETS OR CHANGES THE WHOLESALE ACQUISITION COST OF THE PRESCRIPTION DRUG PRODUCT IT MANUFACTURES OR MARKETS.

(H) "PRESCRIPTION DRUG PRODUCT" MEANS A BRAND NAME DRUG, A GENERIC DRUG, A BIOLOGIC, OR A BIOSIMILAR.

(I) "STAKEHOLDER COUNCIL" MEANS THE PRESCRIPTION DRUG AFFORDABILITY STAKEHOLDER COUNCIL.

21–2C–02.

(A) (1) THERE IS A PRESCRIPTION DRUG AFFORDABILITY BOARD.

(2) (I) THE BOARD IS A BODY POLITIC AND CORPORATE AND IS AN INSTRUMENTALITY OF THE STATE.

(II) THE BOARD IS AN INDEPENDENT UNIT OF STATE GOVERNMENT.

(III) THE EXERCISE BY THE BOARD OF ITS AUTHORITY UNDER THIS SUBTITLE IS AN ESSENTIAL GOVERNMENTAL FUNCTION.

(B) THE PURPOSE OF THE BOARD IS TO PROTECT STATE RESIDENTS, STATE AND LOCAL GOVERNMENTS, COMMERCIAL HEALTH PLANS, HEALTH CARE PROVIDERS, PHARMACIES LICENSED IN THE STATE, AND OTHER STAKEHOLDERS WITHIN THE HEALTH CARE SYSTEM FROM THE HIGH COSTS OF PRESCRIPTION DRUG PRODUCTS.

21–2C–03.

(A) (1) THE BOARD CONSISTS OF THE FOLLOWING MEMBERS, WHO MUST HAVE EXPERTISE IN HEALTH CARE ECONOMICS OR CLINICAL MEDICINE:

(I) ONE MEMBER APPOINTED BY THE GOVERNOR;

(II) ONE MEMBER APPOINTED BY THE PRESIDENT OF THE SENATE;

(III) ONE MEMBER APPOINTED BY THE SPEAKER OF THE HOUSE OF DELEGATES;

(IV) ONE MEMBER APPOINTED BY THE ATTORNEY GENERAL; AND

(V) ONE MEMBER APPOINTED JOINTLY BY THE PRESIDENT OF THE SENATE AND THE SPEAKER OF THE HOUSE OF DELEGATES, WHO SHALL SERVE AS CHAIR OF THE BOARD.

(2) THE BOARD SHALL HAVE THE FOLLOWING ALTERNATE MEMBERS, WHO MUST HAVE EXPERTISE IN HEALTH CARE ECONOMICS OR CLINICAL MEDICINE AND WHO SHALL BE DESIGNATED BY THE BOARD CHAIR TO PARTICIPATE IN DELIBERATIONS OF THE BOARD WHEN A MEMBER IS RECUSED:

(I) ONE ALTERNATE MEMBER APPOINTED BY THE GOVERNOR;

(II) ONE ALTERNATE MEMBER APPOINTED BY THE PRESIDENT OF THE SENATE; AND

(III) ONE ALTERNATE MEMBER APPOINTED BY THE SPEAKER OF THE HOUSE OF DELEGATES.

(3) A MEMBER OR AN ALTERNATE MEMBER MAY NOT BE AN EMPLOYEE OF, A BOARD MEMBER OF, OR A CONSULTANT TO A MANUFACTURER OR TRADE ASSOCIATION FOR MANUFACTURERS.

(4) ANY CONFLICT OF INTEREST, INCLUDING WHETHER THE INDIVIDUAL HAS AN ASSOCIATION, INCLUDING A FINANCIAL OR PERSONAL ASSOCIATION, THAT HAS THE POTENTIAL TO BIAS OR HAS THE APPEARANCE OF BIASING AN INDIVIDUAL'S DECISION IN MATTERS RELATED TO THE BOARD OR THE CONDUCT OF THE BOARD'S ACTIVITIES, SHALL BE CONSIDERED AND DISCLOSED WHEN APPOINTING MEMBERS AND ALTERNATE MEMBERS TO THE BOARD.

(5) TO THE EXTENT PRACTICABLE AND CONSISTENT WITH FEDERAL AND STATE LAW, THE MEMBERSHIP OF THE BOARD SHALL REFLECT THE RACIAL, ETHNIC, AND GENDER DIVERSITY OF THE STATE.

(B) (1) THE TERM OF A MEMBER OR AN ALTERNATE MEMBER IS 5 YEARS.

(2) THE TERMS OF THE MEMBERS AND ALTERNATE MEMBERS ARE STAGGERED AS REQUIRED BY THE TERMS PROVIDED FOR MEMBERS ON OCTOBER 1, 2019.

(C) (1) THE CHAIR SHALL HIRE AN EXECUTIVE DIRECTOR, GENERAL COUNSEL, AND STAFF FOR THE BOARD.

(2) STAFF OF THE BOARD SHALL RECEIVE A SALARY AS PROVIDED IN THE BUDGET OF THE BOARD.

(D) A MEMBER OF THE BOARD:

(1) MAY RECEIVE COMPENSATION AS A MEMBER OF THE BOARD IN ACCORDANCE WITH THE STATE BUDGET; AND

(2) IS ENTITLED TO REIMBURSEMENT FOR EXPENSES UNDER THE STANDARD STATE TRAVEL REGULATIONS, AS PROVIDED IN THE STATE BUDGET.

(E) (1) (I) SUBJECT TO SUBPARAGRAPHS (II) AND (IV) OF THIS PARAGRAPH, THE BOARD SHALL MEET IN OPEN SESSION AT LEAST ONCE EVERY 6 WEEKS TO REVIEW PRESCRIPTION DRUG PRODUCT INFORMATION.

(II) THE CHAIR MAY CANCEL OR POSTPONE A MEETING IF THERE ARE NO PRESCRIPTION DRUG PRODUCTS TO REVIEW.

(III) THE FOLLOWING ACTIONS BY THE BOARD SHALL BE MADE IN OPEN SESSION:

1. DELIBERATIONS ON WHETHER TO SUBJECT A PRESCRIPTION DRUG PRODUCT TO A COST REVIEW UNDER § 21–2C–07(D) OF THIS SUBTITLE;

2. ANY VOTE ON WHETHER TO IMPOSE AN UPPER PAYMENT LIMIT ON PURCHASES AND PAYOR REIMBURSEMENTS OF PRESCRIPTION DRUG PRODUCTS IN THE STATE; AND

3. ANY DECISION BY THE BOARD.

(IV) NOTWITHSTANDING THE OPEN MEETINGS ACT, THE BOARD MAY MEET IN CLOSED SESSION TO DISCUSS PROPRIETARY DATA AND INFORMATION.

(2) THE BOARD SHALL PROVIDE PUBLIC NOTICE OF EACH BOARD MEETING AT LEAST 2 WEEKS IN ADVANCE OF THE MEETING.

(3) MATERIALS FOR EACH BOARD MEETING SHALL BE MADE AVAILABLE TO THE PUBLIC AT LEAST 1 WEEK IN ADVANCE OF THE MEETING.

(4) THE BOARD SHALL PROVIDE AN OPPORTUNITY FOR PUBLIC COMMENT AT EACH OPEN MEETING OF THE BOARD.

(5) THE BOARD SHALL PROVIDE THE PUBLIC WITH THE OPPORTUNITY TO PROVIDE WRITTEN COMMENTS ON PENDING DECISIONS OF THE BOARD.

(6) THE BOARD MAY ALLOW EXPERT TESTIMONY AT BOARD MEETINGS, INCLUDING WHEN THE BOARD MEETS IN CLOSED SESSION.

(7) TO THE EXTENT PRACTICABLE, THE BOARD SHALL ACCESS PRICING INFORMATION FOR PRESCRIPTION DRUG PRODUCTS BY:

(I) ENTERING INTO A MEMORANDUM OF UNDERSTANDING WITH ANOTHER STATE TO WHICH MANUFACTURERS ALREADY REPORT PRICING INFORMATION; AND

(II) ACCESSING OTHER AVAILABLE PRICING INFORMATION.

(8) A MAJORITY OF THE MEMBERS OF THE BOARD CONSTITUTES A QUORUM.

(9) (I) MEMBERS OF THE BOARD SHALL RECUSE THEMSELVES FROM DECISIONS RELATED TO A PRESCRIPTION DRUG PRODUCT IF THE MEMBER, OR AN IMMEDIATE FAMILY MEMBER OF THE MEMBER, HAS RECEIVED OR COULD RECEIVE ANY OF THE FOLLOWING:

1. A DIRECT FINANCIAL BENEFIT OF ANY AMOUNT DERIVING FROM THE RESULT OR FINDING OF A STUDY OR DETERMINATION BY OR FOR THE BOARD; OR

2. A FINANCIAL BENEFIT FROM ANY PERSON THAT OWNS, MANUFACTURES, OR PROVIDES PRESCRIPTION DRUG PRODUCTS, SERVICES, OR ITEMS TO BE STUDIED BY THE BOARD THAT IN THE AGGREGATE EXCEEDS $5,000 PER YEAR.

(II) FOR THE PURPOSES OF SUBPARAGRAPH (I) OF THIS PARAGRAPH, A FINANCIAL BENEFIT INCLUDES HONORARIA, FEES, STOCK, THE VALUE OF THE MEMBER'S OR IMMEDIATE FAMILY MEMBER'S STOCK HOLDINGS, AND ANY DIRECT FINANCIAL BENEFIT DERIVING FROM THE FINDING OF A REVIEW CONDUCTED UNDER THIS SUBTITLE.

(F) IN ADDITION TO THE POWERS SET FORTH ELSEWHERE IN THIS SUBTITLE, THE BOARD MAY:

(1) ADOPT REGULATIONS TO CARRY OUT THE PROVISIONS OF THIS SUBTITLE; AND

(2) ENTER INTO A CONTRACT WITH A QUALIFIED, INDEPENDENT THIRD PARTY FOR ANY SERVICE NECESSARY TO CARRY OUT THE POWERS AND DUTIES OF THE BOARD.

(G) UNLESS PERMISSION IS GRANTED BY THE BOARD, A THIRD PARTY HIRED BY THE BOARD IN ACCORDANCE WITH SUBSECTION (F)(2) OF THIS SECTION MAY NOT RELEASE, PUBLISH, OR OTHERWISE USE ANY INFORMATION TO WHICH THE THIRD PARTY HAS ACCESS UNDER ITS CONTRACT.

(H) (1) EXCEPT AS PROVIDED IN PARAGRAPH (2) OF THIS SUBSECTION, ANY PROCUREMENT FOR SERVICES TO BE PERFORMED OR FOR SUPPLIES TO BE DELIVERED TO THE BOARD IS NOT SUBJECT TO DIVISION II OF THE STATE FINANCE AND PROCUREMENT ARTICLE.

(2) THE BOARD IS SUBJECT TO THE FOLLOWING PROVISIONS OF THE STATE FINANCE AND PROCUREMENT ARTICLE:

(I) TITLE 3A, SUBTITLE 3 (INFORMATION PROCESSING), TO THE EXTENT THAT THE SECRETARY OF INFORMATION TECHNOLOGY DETERMINES THAT AN INFORMATION TECHNOLOGY PROJECT OF THE EXCHANGE IS A MAJOR INFORMATION TECHNOLOGY DEVELOPMENT PROJECT;

(II) TITLE 12, SUBTITLE 4 (POLICIES AND PROCEDURES FOR EXEMPT UNITS); AND

(III) TITLE 14, SUBTITLE 3 (MINORITY BUSINESS PARTICIPATION).

21–2C–04.

(A) THERE IS A PRESCRIPTION DRUG AFFORDABILITY STAKEHOLDER COUNCIL.

(B) THE PURPOSE OF THE STAKEHOLDER COUNCIL IS TO PROVIDE STAKEHOLDER INPUT TO ASSIST THE BOARD IN MAKING DECISIONS AS REQUIRED UNDER THIS SUBTITLE.

(C) (1) THE STAKEHOLDER COUNCIL CONSISTS OF 21 MEMBERS APPOINTED IN ACCORDANCE WITH THIS SUBSECTION.

(2) THE SPEAKER OF THE HOUSE OF DELEGATES SHALL APPOINT:

(I) ONE REPRESENTATIVE OF A STATEWIDE HEALTH CARE ADVOCACY COALITION;

(II) ONE REPRESENTATIVE OF A STATEWIDE ADVOCACY ORGANIZATION FOR SENIORS;

(III) ONE REPRESENTATIVE OF A STATEWIDE ORGANIZATION FOR DIVERSE COMMUNITIES;

(IV) ONE REPRESENTATIVE OF A LABOR UNION;

(V) TWO HEALTH SERVICES RESEARCHERS SPECIALIZING IN PRESCRIPTION DRUGS; AND

(VI) ONE PUBLIC MEMBER AT THE DISCRETION OF THE SPEAKER OF THE HOUSE OF DELEGATES.

(3) THE PRESIDENT OF THE SENATE SHALL APPOINT:

(I) ONE REPRESENTATIVE OF DOCTORS;

(II) ONE REPRESENTATIVE OF NURSES;

(III) ONE REPRESENTATIVE OF HOSPITALS;

(IV) ONE REPRESENTATIVE OF HEALTH INSURERS;

(V) ONE REPRESENTATIVE OF THE DEPARTMENT OF BUDGET AND MANAGEMENT;

(VI) ONE CLINICAL RESEARCHER; AND

(VII) ONE PUBLIC MEMBER AT THE DISCRETION OF THE PRESIDENT OF THE SENATE.

(4) THE GOVERNOR SHALL APPOINT:

(I) ONE REPRESENTATIVE OF BRAND NAME DRUG CORPORATIONS;

(II) ONE REPRESENTATIVE OF GENERIC DRUG CORPORATIONS;

(III) ONE REPRESENTATIVE OF EMPLOYERS;

(IV) ONE REPRESENTATIVE OF PHARMACY BENEFITS MANAGERS;

(V) ONE REPRESENTATIVE OF PHARMACISTS;

(VI) ONE PHARMACOLOGIST; AND

(VII) ONE PUBLIC MEMBER AT THE DISCRETION OF THE GOVERNOR.

(5) THE MEMBERS OF THE STAKEHOLDER COUNCIL SHALL HAVE KNOWLEDGE IN ONE OR MORE OF THE FOLLOWING:

(I) THE PHARMACEUTICAL BUSINESS MODEL;

(II) SUPPLY CHAIN BUSINESS MODELS;

(III) THE PRACTICE OF MEDICINE OR CLINICAL TRAINING;

(IV) CONSUMER OR PATIENT PERSPECTIVES;

(V) HEALTH CARE COSTS TRENDS AND DRIVERS;

(VI) CLINICAL AND HEALTH SERVICES RESEARCH; OR

(VII) THE STATE'S HEALTH CARE MARKETPLACE.

(6) TO THE EXTENT PRACTICABLE AND CONSISTENT WITH FEDERAL AND STATE LAW, THE MEMBERSHIP OF THE STAKEHOLDER COUNCIL SHALL REFLECT THE RACIAL, ETHNIC, AND GENDER DIVERSITY OF THE STATE.

(7) FROM AMONG THE MEMBERSHIP OF THE STAKEHOLDER COUNCIL, THE BOARD CHAIR SHALL APPOINT TWO MEMBERS TO BE COCHAIRS OF THE STAKEHOLDER COUNCIL.

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

(2) THE INITIAL MEMBERS OF THE STAKEHOLDER COUNCIL SHALL SERVE STAGGERED TERMS AS REQUIRED BY THE TERMS PROVIDED FOR MEMBERS ON OCTOBER 1, 2019.

(E) A MEMBER OF THE STAKEHOLDER COUNCIL:

(1) MAY NOT RECEIVE COMPENSATION AS A MEMBER OF THE STAKEHOLDER COUNCIL; BUT

(2) IS ENTITLED TO REIMBURSEMENT FOR EXPENSES UNDER THE STANDARD STATE TRAVEL REGULATIONS, AS PROVIDED IN THE STATE BUDGET.

21–2C–05.

(A) (1) A CONFLICT OF INTEREST SHALL BE DISCLOSED:

(I) BY THE BOARD WHEN HIRING BOARD STAFF;

(II) BY THE APPOINTING AUTHORITY WHEN APPOINTING MEMBERS AND ALTERNATE MEMBERS TO THE BOARD AND MEMBERS TO THE STAKEHOLDER COUNCIL; AND

(III) BY THE BOARD, WHEN A MEMBER OF THE BOARD IS RECUSED IN ANY FINAL DECISION RESULTING FROM A REVIEW OF A PRESCRIPTION DRUG PRODUCT.

(2) A CONFLICT OF INTEREST SHALL BE DISCLOSED:

(I) IN ADVANCE OF THE FIRST OPEN MEETING AFTER THE CONFLICT IS IDENTIFIED; OR

(II) WITHIN 5 DAYS AFTER THE CONFLICT IS IDENTIFIED.

(B) (1) A CONFLICT OF INTEREST DISCLOSED UNDER SUBSECTION (A) OF THIS SECTION SHALL BE POSTED ON THE WEBSITE OF THE BOARD UNLESS THE

CHAIR OF THE BOARD RECUSES THE MEMBER FROM ANY FINAL DECISION RESULTING FROM A REVIEW OF A PRESCRIPTION DRUG PRODUCT.

(2) A POSTING UNDER PARAGRAPH (1) OF THIS SUBSECTION SHALL INCLUDE THE TYPE, NATURE, AND MAGNITUDE OF THE INTERESTS OF THE MEMBER INVOLVED.

21–2C–06.

MEMBERS AND ALTERNATE MEMBERS OF THE BOARD, BOARD STAFF, AND THIRD–PARTY CONTRACTORS MAY NOT ACCEPT ANY GIFT OR DONATION OF SERVICES OR PROPERTY THAT INDICATES A POTENTIAL CONFLICT OF INTEREST OR HAS THE APPEARANCE OF BIASING THE WORK OF THE BOARD.

21–2C–07.

(A) THIS SECTION MAY NOT BE CONSTRUED TO PREVENT A MANUFACTURER FROM MARKETING A PRESCRIPTION DRUG PRODUCT APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION WHILE THE PRODUCT IS UNDER REVIEW BY THE BOARD.

(B) THE BOARD SHALL IDENTIFY PRESCRIPTION DRUG PRODUCTS THAT ARE:

(1) BRAND NAME DRUGS OR BIOLOGICS THAT, AS ADJUSTED ANNUALLY FOR INFLATION IN ACCORDANCE WITH THE CONSUMER PRICE INDEX, HAVE:

(I) A LAUNCH WHOLESALE ACQUISITION COST OF $30,000 OR MORE PER YEAR OR COURSE OF TREATMENT; OR

(II) A WHOLESALE ACQUISITION COST INCREASE OF $3,000 OR MORE IN ANY 12–MONTH PERIOD, OR COURSE OF TREATMENT IF LESS THAN 12 MONTHS;

(2) BIOSIMILAR DRUGS THAT HAVE A LAUNCH WHOLESALE ACQUISITION COST THAT IS NOT AT LEAST 15% LOWER THAN THE REFERENCED BRAND BIOLOGIC AT THE TIME THE BIOSIMILARS ARE LAUNCHED;

(3) GENERIC DRUGS THAT, AS ADJUSTED ANNUALLY FOR INFLATION IN ACCORDANCE WITH THE CONSUMER PRICE INDEX, HAVE A WHOLESALE ACQUISITION COST:

(I) OF $100 OR MORE FOR:

1. A 30–DAY SUPPLY LASTING A PATIENT FOR A PERIOD OF 30 CONSECUTIVE DAYS BASED ON THE RECOMMENDED DOSAGE APPROVED FOR LABELING BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION;

2. A SUPPLY LASTING A PATIENT FOR FEWER THAN 30 DAYS BASED ON THE RECOMMENDED DOSAGE APPROVED FOR LABELING BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION; OR

3. ONE UNIT OF THE DRUG IF THE LABELING APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION DOES NOT RECOMMEND A FINITE DOSAGE; AND

(II) THAT INCREASED BY 200% OR MORE DURING THE IMMEDIATELY PRECEDING 12–MONTH PERIOD, AS DETERMINED BY THE DIFFERENCE BETWEEN THE RESULTING WHOLESALE ACQUISITION COST AND THE AVERAGE OF THE WHOLESALE ACQUISITION COST REPORTED OVER THE IMMEDIATELY PRECEDING 12 MONTHS; AND

(4) OTHER PRESCRIPTION DRUG PRODUCTS THAT MAY CREATE AFFORDABILITY CHALLENGES FOR THE STATE HEALTH CARE SYSTEM AND PATIENTS, IN CONSULTATION WITH THE STAKEHOLDER COUNCIL.

(C) (1) AFTER IDENTIFYING PRESCRIPTION DRUG PRODUCTS AS REQUIRED BY SUBSECTION (B) OF THIS SECTION, THE BOARD SHALL DETERMINE WHETHER TO CONDUCT A COST REVIEW AS DESCRIBED IN SUBSECTION (D) OF THIS SECTION FOR EACH IDENTIFIED PRESCRIPTION DRUG PRODUCT BY:

(I) SEEKING STAKEHOLDER COUNCIL INPUT ABOUT THE PRESCRIPTION DRUG PRODUCT; AND

(II) CONSIDERING THE AVERAGE COST SHARE OF THE PRESCRIPTION DRUG PRODUCT.

(2) (I) TO THE EXTENT THERE IS NO PUBLICLY AVAILABLE INFORMATION TO CONDUCT A COST REVIEW AS DESCRIBED IN SUBSECTION (D) OF THIS SECTION, THE BOARD SHALL REQUEST THE INFORMATION FROM THE MANUFACTURER OF THE PRESCRIPTION DRUG PRODUCT.

(II) THE INFORMATION TO CONDUCT A COST REVIEW MAY INCLUDE ANY DOCUMENT AND RESEARCH RELATED TO THE MANUFACTURER'S SELECTION OF THE INTRODUCTORY PRICE OR PRICE INCREASE OF THE

PRESCRIPTION DRUG PRODUCT, INCLUDING LIFE CYCLE MANAGEMENT, NET AVERAGE PRICE IN THE STATE, MARKET COMPETITION AND CONTEXT, PROJECTED REVENUE, AND THE ESTIMATED VALUE OR COST–EFFECTIVENESS OF THE PRESCRIPTION DRUG PRODUCT.

(III) FAILURE OF A MANUFACTURER TO PROVIDE THE BOARD WITH THE INFORMATION REQUESTED UNDER THIS PARAGRAPH DOES NOT AFFECT THE AUTHORITY OF THE BOARD TO CONDUCT A REVIEW AS DESCRIBED IN SUBSECTION (D) OF THIS SECTION OR ESTABLISH AN UPPER PAYMENT LIMIT AS AUTHORIZED UNDER SUBSECTION (E) OF THIS SECTION.

(D) (1) IF THE BOARD CONDUCTS A REVIEW OF THE COST OF A PRESCRIPTION DRUG PRODUCT, THE REVIEW SHALL DETERMINE WHETHER USE OF THE PRESCRIPTION DRUG PRODUCT THAT IS FULLY CONSISTENT WITH THE LABELING APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION OR STANDARD MEDICAL PRACTICE HAS LED OR WILL LEAD TO AFFORDABILITY CHALLENGES FOR THE STATE HEALTH CARE SYSTEM OR HIGH OUT–OF–POCKET COSTS FOR PATIENTS.

(2) TO THE EXTENT PRACTICABLE, IN DETERMINING WHETHER A PRESCRIPTION DRUG PRODUCT IDENTIFIED UNDER SUBSECTION (B) OF THIS SECTION HAS LED OR WILL LEAD TO AN AFFORDABILITY CHALLENGE, THE BOARD SHALL CONSIDER THE FOLLOWING FACTORS:

(I) THE WHOLESALE ACQUISITION COST FOR THE PRESCRIPTION DRUG PRODUCT SOLD IN THE STATE;

(II) THE AVERAGE MONETARY PRICE CONCESSION, DISCOUNT, OR REBATE THE MANUFACTURER PROVIDES TO HEALTH PLANS IN THE STATE OR IS EXPECTED TO PROVIDE TO HEALTH PLANS IN THE STATE AS REPORTED BY MANUFACTURERS AND HEALTH PLANS, EXPRESSED AS A PERCENT OF THE WHOLESALE ACQUISITION COST FOR THE PRESCRIPTION DRUG PRODUCT UNDER REVIEW;

(III) THE TOTAL AMOUNT OF THE PRICE CONCESSION, DISCOUNT, OR REBATE THE MANUFACTURER PROVIDES TO EACH PHARMACY BENEFITS MANAGER OPERATING IN THE STATE FOR THE PRESCRIPTION DRUG PRODUCT UNDER REVIEW, AS REPORTED BY MANUFACTURERS AND PHARMACY BENEFITS MANAGERS, EXPRESSED AS A PERCENT OF THE WHOLESALE ACQUISITION COSTS;

(IV) THE PRICE AT WHICH THERAPEUTIC ALTERNATIVES HAVE BEEN SOLD IN THE STATE;

(V) THE AVERAGE MONETARY CONCESSION, DISCOUNT, OR REBATE THE MANUFACTURER PROVIDES OR IS EXPECTED TO PROVIDE TO HEALTH PLAN PAYORS AND PHARMACY BENEFITS MANAGERS IN THE STATE FOR THERAPEUTIC ALTERNATIVES;

(VI) THE COSTS TO HEALTH PLANS BASED ON PATIENT ACCESS CONSISTENT WITH UNITED STATES FOOD AND DRUG ADMINISTRATION LABELED INDICATIONS;

(VII) THE IMPACT ON PATIENT ACCESS RESULTING FROM THE COST OF THE PRESCRIPTION DRUG PRODUCT RELATIVE TO INSURANCE BENEFIT DESIGN;

(VIII) THE CURRENT OR EXPECTED DOLLAR VALUE OF DRUG–SPECIFIC PATIENT ACCESS PROGRAMS THAT ARE SUPPORTED BY THE MANUFACTURER;

(IX) THE RELATIVE FINANCIAL IMPACTS TO HEALTH, MEDICAL, OR SOCIAL SERVICES COSTS AS CAN BE QUANTIFIED AND COMPARED TO BASELINE EFFECTS OF EXISTING THERAPEUTIC ALTERNATIVES;

(X) THE AVERAGE PATIENT COPAY OR OTHER COST–SHARING FOR THE PRESCRIPTION DRUG PRODUCT IN THE STATE; AND

(XI) ANY OTHER FACTORS AS DETERMINED BY THE BOARD IN REGULATIONS ADOPTED BY THE BOARD.

(3) IF THE BOARD IS UNABLE TO DETERMINE WHETHER A PRESCRIPTION DRUG PRODUCT WILL PRODUCE OR HAS PRODUCED CHALLENGES TO THE AFFORDABILITY OF THE DRUG FOR THE STATE HEALTH CARE SYSTEM, USING THE FACTORS LISTED IN PARAGRAPH (2) OF THIS SUBSECTION, THE BOARD MAY CONSIDER THE FOLLOWING FACTORS:

(I) THE MANUFACTURER'S RESEARCH AND DEVELOPMENT COSTS, AS INDICATED ON THE MANUFACTURER'S FEDERAL TAX FILING OR INFORMATION FILED WITH THE FEDERAL SECURITIES AND EXCHANGE COMMISSION FOR THE MOST RECENT TAX YEAR IN PROPORTION TO THE MANUFACTURER'S SALES IN THE STATE;

(II) THE PORTION OF DIRECT–TO–CONSUMER MARKETING COSTS ELIGIBLE FOR FAVORABLE FEDERAL TAX TREATMENT IN THE MOST RECENT TAX YEAR THAT ARE SPECIFIC TO THE PRESCRIPTION DRUG PRODUCT UNDER

REVIEW AND THAT ARE MULTIPLIED BY THE RATIO OF TOTAL MANUFACTURER IN–STATE SALES TO TOTAL MANUFACTURER SALES IN THE UNITED STATES FOR THE PRODUCT UNDER REVIEW;

(III) GROSS AND NET MANUFACTURER REVENUES FOR THE MOST RECENT TAX YEAR;

(IV) ANY ADDITIONAL FACTORS PROPOSED BY THE MANUFACTURER THAT THE BOARD CONSIDERS RELEVANT; AND

(V) ANY ADDITIONAL FACTORS AS ESTABLISHED BY THE BOARD IN REGULATIONS.

(E) (1) IF THE BOARD FINDS THAT THE SPENDING ON A PRESCRIPTION DRUG PRODUCT REVIEWED UNDER THIS SECTION HAS LED OR WILL LEAD TO AN AFFORDABILITY CHALLENGE, THE BOARD SHALL RECOMMEND OR ESTABLISH AN UPPER PAYMENT LIMIT UNDER PARAGRAPH (2) OR (3) OF THIS SUBSECTION AFTER CONSIDERING:

(I) THE COST OF ADMINISTERING THE DRUG;

(II) THE COST OF DELIVERING THE DRUG TO CONSUMERS;

(III) OTHER RELEVANT ADMINISTRATIVE COSTS RELATED TO THE DRUG; AND

(IV) IF APPLICABLE, ANY METHODOLOGIES OR DATA SOURCES IDENTIFIED UNDER PARAGRAPH (2)(I) OF THIS SUBSECTION.

(2) ON OR BEFORE DECEMBER 31, 2023, THE BOARD SHALL WORK WITH PAYORS, PURCHASERS, CONSUMERS, AND OTHER STAKEHOLDERS TO:

(I) REFINE METHODOLOGIES BY WHICH TO SET UPPER PAYMENT LIMITS FOR PRESCRIPTION DRUG PRODUCTS; AND

(II) ESTABLISH DATA SOURCES FOR CONDUCTING ANALYSIS OF THE NEED FOR UPPER PAYMENT LIMITS FOR SPECIFIC DRUGS, INCLUDING MEMORANDA OF UNDERSTANDING WITH STATES THAT REQUIRE RELEVANT MANUFACTURER REPORTING.

(3) ON OR BEFORE DECEMBER 31, 2023, THE BOARD SHALL:

(I) CONSIDER ALL OF THE INFORMATION THE BOARD RECEIVES UNDER THIS SECTION; AND

(II) RECOMMEND AND PUBLICIZE AN UPPER PAYMENT LIMIT THAT APPLIES TO ALL PURCHASES AND PAYOR REIMBURSEMENTS OF THE PRESCRIPTION DRUG PRODUCT IN THE STATE.

(4) BEGINNING JANUARY 1, 2024, THE BOARD SHALL:

(I) FOR A PRESCRIPTION DRUG PRODUCT FOR WHICH THE BOARD RECOMMENDED AN UPPER PAYMENT LIMIT UNDER PARAGRAPH (3)(II) OF THIS SUBSECTION:

1. CONSIDER ANY ADDITIONAL METHODOLOGIES OR DATA SOURCES THAT HAVE BEEN IDENTIFIED UNDER PARAGRAPH (1)(I) OF THIS SUBSECTION; AND

2. DETERMINE WHETHER TO ESTABLISH AN UPPER PAYMENT LIMIT THAT APPLIES TO ALL PURCHASES AND PAYOR REIMBURSEMENTS OF THE PRESCRIPTION DRUG PRODUCT IN THE STATE; AND

(II) FOR ANY OTHER PRESCRIPTION DRUG PRODUCT THE BOARD REVIEWS UNDER THIS SECTION AND DETERMINES CREATES AFFORDABILITY CHALLENGES FOR THE STATE HEALTH CARE SYSTEM AND PATIENTS:

1. CONSIDER ALL OF THE INFORMATION THE BOARD RECEIVES UNDER THIS SECTION; AND

2. ESTABLISH AN UPPER PAYMENT LIMIT THAT APPLIES TO ALL PURCHASES AND PAYOR REIMBURSEMENTS OF THE PRESCRIPTION DRUG PRODUCT IN THE STATE.

(5) A RECOMMENDATION FOR AN UPPER PAYMENT LIMIT MADE UNDER PARAGRAPH (3)(II) OF THIS SUBSECTION MAY NOT BE ENFORCED UNLESS IT IS ESTABLISHED UNDER PARAGRAPH (4)(I) OF THIS SUBSECTION.

(F) ANY INFORMATION SUBMITTED TO THE BOARD IN ACCORDANCE WITH THIS SECTION SHALL BE SUBJECT TO PUBLIC INSPECTION ONLY TO THE EXTENT ALLOWED UNDER THE PUBLIC INFORMATION ACT.

21–2C–08.

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

21–2C–09.

(A) A PERSON AGGRIEVED BY A DECISION OF THE BOARD MAY REQUEST AN APPEAL OF THE DECISION WITHIN 30 DAYS AFTER THE FINDING OF THE BOARD.

(B) THE BOARD SHALL HEAR THE APPEAL AND MAKE A FINAL DECISION WITHIN 60 DAYS AFTER THE APPEAL IS REQUESTED.

(C) ANY PERSON AGGRIEVED BY A FINAL DECISION OF THE BOARD MAY PETITION FOR JUDICIAL REVIEW AS PROVIDED BY THE ADMINISTRATIVE PROCEDURE ACT.

21–2C–10.

(A) IN THIS SECTION, "FUND" MEANS THE PRESCRIPTION DRUG AFFORDABILITY FUND.

(B) (1) THERE IS A PRESCRIPTION DRUG AFFORDABILITY FUND.

(2) THE FUND IS A SPECIAL, NONLAPSING FUND THAT IS NOT SUBJECT TO § 7–302 OF THE STATE FINANCE AND PROCUREMENT ARTICLE.

(C) (1) SUBJECT TO SUBSECTION (D) OF THIS SECTION, THE BOARD SHALL BE FUNDED BY AN ASSESSMENT ON ALL MANUFACTURERS.

(2) THE BOARD SHALL ASSESS AND COLLECT FEES FROM MANUFACTURERS AS PROVIDED FOR IN THIS SECTION.

(3) THE BOARD SHALL ASSESS EACH MANUFACTURER ON THE MANUFACTURER'S RELATIVE SHARE OF GROSS REVENUE FROM DRUG SALES IN THE STATE.

(4) EACH YEAR, A MANUFACTURER ASSESSED UNDER THIS SECTION SHALL PAY A FEE TO THE BOARD.

(5) THE BOARD SHALL PAY ALL FUNDS COLLECTED FROM THE ASSESSMENT INTO THE FUND.

(6) THE STATE TREASURER SHALL HOLD THE FUND SEPARATELY, AND THE COMPTROLLER SHALL ACCOUNT FOR THE FUND.

(7) THE FUND SHALL BE USED ONLY TO PROVIDE FUNDING FOR THE BOARD AND FOR THE PURPOSES AUTHORIZED UNDER THIS SUBTITLE INCLUDING ANY COSTS EXPENDED BY ANY STATE AGENCY TO IMPLEMENT THIS SUBTITLE.

(8) THE FUND SHALL BE INVESTED AND REINVESTED IN THE SAME MANNER AS OTHER STATE FUNDS.

(9) ANY INVESTMENT EARNINGS SHALL BE RETAINED TO THE CREDIT OF THE FUND.

(10) THE FUND SHALL BE SUBJECT TO AN AUDIT BY THE OFFICE OF LEGISLATIVE AUDITS AS PROVIDED FOR UNDER § 2–1220 OF THE STATE GOVERNMENT ARTICLE.

(11) THIS SUBSECTION MAY NOT BE CONSTRUED TO PROHIBIT THE FUND FROM RECEIVING FUNDS FROM ANY OTHER SOURCE.

(D) THE BOARD SHALL BE ESTABLISHED USING GENERAL FUNDS, WHICH SHALL BE REPAID TO THE STATE WITH THE ASSESSMENTS REQUIRED UNDER THIS SECTION.

21–2C–11.

ON OR BEFORE DECEMBER 31 EACH YEAR, 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, INCLUDING THE RESULTS OF THE REVIEW AND THE NUMBER AND DISPOSITION OF APPEALS AND JUDICIAL REVIEWS OF BOARD DECISIONS; AND

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

Article – State Finance and Procurement

6–226.

(a) (2) (i) Notwithstanding any other provision of law, and unless inconsistent with a federal law, grant agreement, or other federal requirement or with the terms of a gift or settlement agreement, net interest on all State money allocated by the State Treasurer under this section to special funds or accounts, and otherwise entitled to receive interest earnings, as accounted for by the Comptroller, shall accrue to the General Fund of the State.

(ii) The provisions of subparagraph (i) of this paragraph do not apply to the following funds:

112. the Pretrial Services Program Grant Fund; **[**and**]**

113. the Veteran Employment and Transition Success Fund**; AND**

114. THE PRESCRIPTION DRUG AFFORDABILITY FUND.

SECTION 2. AND BE IT FURTHER ENACTED, That:

(a) The terms of the initial members and alternate members of the Prescription Drug Affordability Board shall expire as follows:

(1) one member and one alternate member in 2022;

(2) two members and one alternate member in 2023; and

(3) two members, including the chair of the Board, and one alternate member in 2024.

(b) The terms of the initial members of the Prescription Drug Affordability Stakeholder Council shall expire as follows:

(1) seven members in 2022;

(2) seven members in 2023; and

(3) seven members in 2024.

SECTION 3. AND BE IT FURTHER ENACTED, That, on or before June 1, 2020, the Prescription Drug Affordability Board shall:

(1) conduct a study of the operation of the generic drug market in the United States that includes a review of physician–administered drugs and considers:

(i) the prices of generic drugs on a year–over–year basis;

(ii) the degree to which generic drug prices affect yearly insurance premium changes;

(iii) annual changes in insurance cost–sharing for generic drugs;

(iv) the potential for and history of drug shortages;

(v) the degree to which generic drug prices affect yearly State Medicaid spending; and

(vi) any other relevant study questions; and

(2) report its findings to the General Assembly, in accordance with § 2–1246 of the State Government Article.

SECTION 4. AND BE IT FURTHER ENACTED, That, on or before January 1, 2023, the Health Services Cost Review Commission, in consultation with the Maryland Health Care Commission, shall:

(1) monitor and assess the impact of upper payment limits and policy actions by the Prescription Drug Affordability Board on:

(i) prescription drug affordability and access to hospital services in the State;

(ii) the ability of hospitals and other providers to obtain drugs from manufacturers and suppliers at costs consistent with the upper payment limits established by the Board; and

(iii) the ability of the State to meet the requirements of the All–Payer Model Contract; and

(2) report its findings and recommendations to the General Assembly, in accordance with § 2–1246 of the State Government Article.

SECTION 5. AND BE IT FURTHER ENACTED, That, if any provision of this Act or the application thereof to any person or circumstance is held invalid for any reason in a court of competent jurisdiction, the invalidity does not affect other provisions or any other application of this Act that can be given effect without the invalid provision or application, and for this purpose the provisions of this Act are declared severable.

SECTION 6. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2019.