HOUSE BILL 1194

J1, J3 8lr1057
CF SB 1023

By: **Delegates Pena–Melnyk, Ali, Anderson, Atterbeary, B. Barnes, D. Barnes, Barron, Barve, Beidle, Branch, Brooks, Carey, Carr, Chang, Clippinger, Conaway, Cullison, Davis, Dumais, Ebersole, Fennell, Fraser–Hidalgo, Frush, Gaines, Gibson, Gilchrist, Glenn, Gutierrez, Hayes, Haynes, Healey, Hettleman, Hill, Hixson, C. Howard, Impallaria, Jackson, Jalisi, Jones, Kaiser, Kelly, Kramer, Lafferty, Lam, J. Lewis, R. Lewis, Lierman, Luedtke, McDonough, McIntosh, A. Miller, Moon, Morales, Morhaim, Mosby, Patterson, Platt, Proctor, Queen, Reznik, Robinson, Rosenberg, Sample–Hughes, Sanchez, Stein, Sydnor, Tarlau, Turner, Valderrama, Valentino–Smith, Vallario, Waldstreicher, Walker, A. Washington, M. Washington, Wilkins, Wilson, K. Young, ~~and P. Young~~ P. Young, Pendergrass, Bromwell, Kipke, Krebs, Metzgar, Miele, Morgan, Saab, Szeliga, and West**

Introduced and read first time: February 8, 2018
Assigned to: Health and Government Operations

Committee Report: Favorable with amendments
House action: Adopted
Read second time: March 27, 2018

CHAPTER _____

AN ACT concerning

Health – Drug Cost ~~Review~~ Commission

FOR the purpose of establishing the Drug Cost ~~Review~~ Commission; providing for the purpose of the Commission; providing for the membership of the Commission; ~~requiring certain conflicts of interest to be disclosed and considered when appointing members to the Commission; specifying the terms of the initial members of the Commission; providing for the election of the chair of the Commission and requiring the chair to hire certain staff; requiring that the staff of the Commission receive a certain salary;~~ requiring the Commission to create a certain advisory council; providing for the staffing of the Commission; prohibiting a member of the Commission from receiving certain compensation, but authorizing the reimbursement of certain expenses; requiring the Commission to meet in a certain manner ~~and with a certain frequency with certain exceptions~~ with a certain

EXPLANATION: **CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.**
[Brackets**]** indicate matter deleted from existing law.
Underlining indicates amendments to bill.
~~Strike out~~ indicates matter stricken from the bill by amendment or deleted from the law by amendment.

exception; requiring the Commission to provide certain public notice of each Commission meeting and to make certain materials available to the public in a certain manner; requiring the Commission to provide the public with the opportunity to provide certain comments; authorizing the Commission to allow expert testimony under certain circumstances; ~~requiring certain actions by the Commission to be made in open session;~~ providing that a majority of the members of the Commission constitutes a quorum; ~~requiring a member of the Commission to recuse the member from certain decisions under certain circumstances; establishing the Drug Cost Review Advisory Board; providing for the purpose of the Advisory Board; providing for the membership of the Advisory Board; requiring certain conflicts of interest to be disclosed and considered when appointing members to the Advisory Board; specifying the terms of the initial members of the Advisory Board; requiring the members of the Advisory Board to elect a chair and cochair; prohibiting a member of the Advisory Board 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; requiring a conflict of interest to be posted on a certain website except under certain circumstances; requiring the posting to include certain information; requiring a member of the Advisory Board to recuse the member from certain decisions under certain circumstances;~~ prohibiting a member of the Commission, a member of the ~~Advisory Board~~ advisory council, Commission staff, or a third–party contractor from accepting certain gifts or donations; ~~requiring certain manufacturers to provide certain notice to the Commission under certain circumstances; requiring the Commission to establish certain reporting thresholds, in consultation with stakeholders and experts; requiring the Commission to access certain information to the extent feasible and practicable; requiring the Commission to require certain manufacturers to submit certain information to the Commission under certain circumstances; requiring the Commission to inform the public about certain reports and to allow the public to make certain requests; requiring the chair of the Commission to review certain requests and initiate a certain review under certain circumstances; authorizing the members of the Commission to request a certain vote under certain circumstances; requiring a certain review by the Commission to make a certain determination; authorizing the Commission to consider certain factors in determining costs and excess costs; authorizing the Commission to establish a certain level of reimbursement if the Commission makes a certain finding; requiring certain submissions to the Commission to be made available to the public; requiring the Commission to establish certain standards related to proprietary information; providing for the referral of certain entities to the Office of the Attorney General under certain circumstances; authorizing the Office of the Attorney General to pursue certain remedies under certain circumstances; requiring the Office of the Attorney General to provide certain guidance to certain stakeholders; authorizing a certain appeal of certain decisions by the Commission; requiring the Commission to be funded in a certain manner; requiring the Commission to determine the amount of a certain assessment; requiring the Commission to make available to the public a certain annual report; defining certain terms; making the provisions of this Act severable;~~ requiring the Commission to access certain information to the extent practicable and feasible; authorizing the Commission to access certain information

by entering into certain agreements to the extent feasible and practicable; prohibiting the Commission from publicly disclosing certain information; requiring that certain information obtained by the Commission be considered confidential commercial information; prohibiting certain information from being released by the Commission in certain manners; providing for the duties of the Commission; requiring the Commission to submit certain reports to certain committees of the General Assembly on or before certain dates; providing for the termination of this Act; and generally relating to the Drug Cost ~~Review~~ Commission.

~~BY adding to~~
~~Article – Health – General~~
~~Section 21–2C–01 through 21–2C–11 to be under the new subtitle "Subtitle 2C. Drug Cost Review Commission"~~
~~Annotated Code of Maryland~~
~~(2015 Replacement Volume and 2017 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 pressure, creating unmanageable costs for consumers across wide market segments, leading to a rising, unsustainable strain on State and commercial 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; now, therefore,~~

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

(a) There is a Drug Cost Commission.

(b) The purpose of the Commission is to determine how to make prescription drugs more affordable for State residents, State and local government, commercial health plans, health care providers, pharmacies licensed in the State, and other stakeholders within the health care system.

(c) The Commission shall consist of the following members:

(1) one member appointed by the Governor;

(2) one member appointed by the President of the Senate;

(3) one member appointed by the Speaker of the House of Delegates;

(4) one member appointed by the Attorney General; and

(5) 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 Commission.

(d) The Commission shall create an advisory council consisting of:

(1) representatives of the prescription drug supply chain, including representatives of the pharmaceutical industry and the generic drug industry;

(2) consumer advocates; and

(3) other representatives as considered necessary by the Commission.

(e) A majority of the members of the Commission constitutes a quorum.

(f) The Department of Legislative Services, in consultation with the Office of the Attorney General, shall provide staff for the Commission.

(g) A member of the Commission:

(1) may not receive compensation as a member of the Commission; but

(2) is entitled to reimbursement for expenses under the Standard State Travel Regulations, as provided in the State budget.

(h) (1) (i) Except as provided in subparagraph (ii) of this paragraph, the Commission shall meet in open session.

(ii) The Commission may meet in closed session when discussing nonpublic pricing information.

(2) Public notice of each Commission meeting shall be provided at least 2 weeks in advance of the meeting.

(3) Materials for each open Commission meeting shall be made available to the public at least 1 week in advance of the meeting.

(4) The Commission shall provide an opportunity for public comment at each open meeting of the Commission.

(5) The Commission shall provide the public with the opportunity to provide written comments on pending decisions of the Commission.

(6) The Commission may allow expert testimony at Commission meetings.

(i) Members of the Commission, members of the advisory council, Commission 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 Commission.

(j) (1) To the extent feasible and practicable, for brand name and generic drugs, the Commission shall access drug pricing justification information that is available to the public from manufacturers, wholesalers, pharmacy benefits managers, insurance carriers, and pharmacies, including any rebates offered on the drugs.

(2) To the extent feasible and practicable, the Commission may access public and nonpublic prescription drug pricing information by entering into a memorandum of understanding with another state.

(3) (i) The Commission may not publicly disclose proprietary information.

(ii) Proprietary information obtained by the Commission under this section shall be considered confidential commercial information, including for purposes of § 4–335 of the General Provisions Article.

(iii) Proprietary information may not be released by the Commission in any manner that:

1. allows for the identification of:

A. an individual drug;

B. a manufacturer; or

C. another entity from which proprietary information was obtained; or

2. is likely to compromise the financial, competitive, or proprietary nature of the information.

(k) The Commission shall:

(1) review, evaluate, and assess the pharmaceutical distribution and payment system in the State;

(2) assess and collect publicly available information from brand and generic biopharmaceutical manufacturers, health insurers, pharmaceutical wholesalers, and pharmacy benefits managers; and

(3) compare the prices for prescription drugs in the United States and in other countries.

(l) On or before January 1, 2019, and each January 1 thereafter, the Commission, in consultation with stakeholders, shall submit a 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) findings related to the prescription drug pricing information accessed by the Commission;

(2) recommendations on how entities within the prescription drug supply chain can improve access to affordable prescription drugs by State residents; and

(3) findings related to the price of prescription drugs in the United States as compared to other countries and recommendations on how to make the prices of drugs in the United States comparable to the price of drugs in other countries.

~~**Article – Health – General**~~

~~**SUBTITLE 2C. DRUG COST REVIEW COMMISSION.**~~

~~**21–2C–01.**~~

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

~~**(B) "ADVISORY BOARD" MEANS THE DRUG COST REVIEW ADVISORY BOARD.**~~

~~**(C) "COMMISSION" MEANS THE DRUG COST REVIEW COMMISSION.**~~

~~(D) "EXCESS COSTS" MEANS COSTS OF APPROPRIATE UTILIZATION OF A PRESCRIPTION DRUG PRODUCT THAT ARE NOT SUSTAINABLE TO PUBLIC AND PRIVATE HEALTH CARE SYSTEMS OVER A 10–YEAR TIME FRAME.~~

~~21–2C–02.~~

~~(A) THERE IS A DRUG COST REVIEW COMMISSION.~~

~~(B) THE PURPOSE OF THE COMMISSION 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 EXCESSIVE COSTS OF PRESCRIPTION DRUGS.~~

~~21–2C–03.~~

~~(A) (1) THE COMMISSION SHALL CONSIST OF THE FOLLOWING MEMBERS WHO HAVE EXPERTISE IN HEALTH CARE ECONOMICS OR CLINICAL MEDICINE:~~

~~(I) ONE MEMBER APPOINTED BY THE GOVERNOR;~~

~~(II) ONE MEMBER APPOINTED BY THE STATE TREASURER;~~

~~(III) ONE MEMBER APPOINTED BY THE PRESIDENT OF THE SENATE;~~

~~(IV) ONE MEMBER APPOINTED BY THE SPEAKER OF THE HOUSE OF DELEGATES; AND~~

~~(V) ONE MEMBER APPOINTED BY THE ATTORNEY GENERAL.~~

~~(2) THE GOVERNOR SHALL APPOINT TWO MEMBERS TO SERVE AS ALTERNATIVE MEMBERS WHO SHALL PARTICIPATE IN DELIBERATIONS OF THE COMMISSION WHEN A MEMBER IS RECUSED.~~

~~(3) ANY POTENTIAL 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 DECISIONS IN MATTERS RELATED TO THE COMMISSION OR THE CONDUCT OF THE COMMISSION'S ACTIVITIES, SHALL BE CONSIDERED AND DISCLOSED WHEN APPOINTING MEMBERS TO THE COMMISSION.~~

~~(B) (1) THE TERM OF A MEMBER IS 5 YEARS.~~

~~(2) THE TERMS OF THE MEMBERS ARE STAGGERED AS REQUIRED BY THE TERMS PROVIDED FOR MEMBERS ON OCTOBER 1, 2018.~~

~~(C) (1) THE CHAIR OF THE COMMISSION SHALL BE ELECTED BY THE MEMBERS OF THE COMMISSION.~~

~~(2) THE CHAIR SHALL HIRE AN EXECUTIVE DIRECTOR, GENERAL COUNSEL, AND STAFF FOR THE COMMISSION.~~

~~(3) STAFF OF THE COMMISSION SHALL RECEIVE A SALARY AS PROVIDED IN THE BUDGET OF THE COMMISSION.~~

~~(D) A MEMBER OF THE COMMISSION:~~

~~(1) MAY NOT RECEIVE COMPENSATION AS A MEMBER OF THE COMMISSION; BUT~~

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

~~(E) (1) (I) EXCEPT AS PROVIDED IN SUBPARAGRAPHS (II) AND (III) OF THIS PARAGRAPH, THE COMMISSION SHALL MEET IN OPEN SESSION AT LEAST EVERY 6 WEEKS TO REVIEW PRESCRIPTION DRUG PRODUCT INFORMATION SUBMISSIONS.~~

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

~~(III) NOTWITHSTANDING THE OPEN MEETINGS ACT, THE COMMISSION MAY MEET IN CLOSED SESSION BUT DECISIONS OF THE COMMISSION SHALL BE MADE IN OPEN SESSION.~~

~~(2) PUBLIC NOTICE OF EACH COMMISSION MEETING SHALL BE PROVIDED AT LEAST 2 WEEKS IN ADVANCE OF THE MEETING.~~

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

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

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

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

~~(7) THE FOLLOWING ACTIONS BY THE COMMISSION SHALL BE MADE IN OPEN SESSION:~~

~~(I) DELIBERATIONS ON WHETHER TO SUBJECT A PRESCRIPTION DRUG TO A FULL COST REVIEW;~~

~~(II) ANY REVIEW OF A PRESCRIPTION DRUG COST ANALYSIS; AND~~

~~(III) ANY VOTE ON WHETHER TO IMPOSE A COST OR PAYMENT LIMIT ON PAYORS FOR A PRESCRIPTION DRUG PRODUCT.~~

~~(8) A MAJORITY OF THE MEMBERS OF THE COMMISSION CONSTITUTES A QUORUM.~~

~~(9) (I) A MEMBER OF THE COMMISSION SHALL RECUSE THE MEMBER FROM THE DECISIONS RELATED TO A PRESCRIPTION DRUG UNDER REVIEW IF THE MEMBER, OR A CLOSE RELATIVE 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 FINDINGS OF A STUDY OR DETERMINATION BY OR FOR THE COMMISSION; OR~~

~~2. A FINANCIAL BENEFIT FROM INDIVIDUALS OR COMPANIES THAT OWN, MANUFACTURE, OR PROVIDE PRESCRIPTION DRUGS, SERVICES, OR ITEMS TO BE STUDIED BY THE COMMISSION THAT IN THE AGGREGATE EXCEEDS $5,000 PER YEAR.~~

~~(II) A FINANCIAL BENEFIT AS DESCRIBED IN SUBPARAGRAPH (I) OF THIS PARAGRAPH INCLUDES HONORARIA, FEES, STOCK, THE VALUE OF THE MEMBER'S OR CLOSE RELATIVE'S STOCK HOLDINGS, AND ANY DIRECT FINANCIAL BENEFIT DERIVING FROM THE FINDINGS OF A REVIEW CONDUCTED UNDER THIS SUBTITLE.~~

~~21–2C–04.~~

~~(A) THERE IS A DRUG COST REVIEW ADVISORY BOARD.~~

~~(B) THE PURPOSE OF THE ADVISORY BOARD IS TO PROVIDE STAKEHOLDER INPUT TO ASSIST THE COMMISSION IN PERFORMING ITS DUTIES.~~

~~(C) (1) THE ADVISORY BOARD SHALL CONSIST OF THE FOLLOWING MEMBERS:~~

~~(I) TWO MEMBERS WHO REPRESENT PATIENTS AND HEALTH CARE CONSUMERS;~~

~~(II) TWO MEMBERS WHO REPRESENT PHYSICIANS AND PROVIDERS;~~

~~(III) THREE MEMBERS WHO REPRESENT COMMERCIAL PAYORS, GOVERNMENT EMPLOYEE BENEFIT PLANS, OR LARGE EMPLOYER PLANS;~~

~~(IV) ONE MEMBER WHO REPRESENTS PHARMACEUTICAL MANUFACTURERS;~~

~~(V) ONE HEALTH SERVICES RESEARCHER;~~

~~(VI) ONE CLINICAL RESEARCHER;~~

~~(VII) ONE PHARMACOLOGIST; AND~~

~~(VIII) ONE REPRESENTATIVE FROM THE DEPARTMENT OF BUDGET AND MANAGEMENT.~~

~~(2) THE MEMBERS OF THE ADVISORY BOARD SHALL HAVE KNOWLEDGE OF ONE OR MORE OF THE FOLLOWING:~~

~~(I) THE PHARMACEUTICAL BUSINESS MODEL;~~

~~(II) THE PRACTICE OF MEDICINE OR CLINICAL TRAINING;~~

~~(III) PATIENT PERSPECTIVES;~~

~~(IV) HEALTH CARE COSTS TRENDS AND DRIVERS;~~

~~(V) CLINICAL AND HEALTH SERVICES RESEARCH; OR~~

~~(VI) THE STATE'S HEALTH CARE MARKETPLACE.~~

~~(3) THE MEMBERS OF THE ADVISORY BOARD SHALL BE APPOINTED AS FOLLOWS:~~

~~(I) FOUR MEMBERS SHALL BE APPOINTED BY THE GOVERNOR;~~

~~(II) FOUR MEMBERS SHALL BE APPOINTED BY THE PRESIDENT OF THE SENATE; AND~~

~~(III) FOUR MEMBERS SHALL BE APPOINTED BY THE SPEAKER OF THE HOUSE OF DELEGATES.~~

~~(4) ANY POTENTIAL 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 DECISIONS IN MATTERS RELATED TO THE COMMISSION OR THE CONDUCT OF THE COMMISSION'S ACTIVITIES, SHALL BE CONSIDERED AND DISCLOSED WHEN MAKING APPOINTMENTS TO THE ADVISORY BOARD.~~

~~(D) (1) THE TERM OF A MEMBER IS 2 YEARS.~~

~~(2) THE INITIAL MEMBERS OF THE ADVISORY BOARD SHALL SERVE STAGGERED TERMS AS REQUIRED BY THE TERMS PROVIDED FOR MEMBERS ON OCTOBER 1, 2018.~~

~~(E) A CHAIR AND COCHAIR SHALL BE ELECTED BY THE MEMBERS OF THE ADVISORY BOARD.~~

~~(F) A MEMBER OF THE ADVISORY BOARD:~~

~~(1) MAY NOT RECEIVE COMPENSATION AS A MEMBER OF THE ADVISORY BOARD; 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 IN THE FOLLOWING MANNER:~~

~~(I) BY THE COMMISSION WHEN HIRING COMMISSION STAFF;~~

~~(II) BY THE APPOINTING AUTHORITY WHEN APPOINTING MEMBERS TO THE COMMISSION AND THE ADVISORY BOARD; AND~~

~~(III) BY THE COMMISSION, DESCRIBING ANY RECUSAL BY A MEMBER OF THE COMMISSION 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 ANY OPEN MEETING; AND~~

~~(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 COMMISSION UNLESS THE MEMBER RECUSES THE MEMBER FROM ANY FINAL DECISION RESULTING FROM A REVIEW OF A PRESCRIPTION DRUG PRODUCT.~~

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

~~21–2C–06.~~

~~MEMBERS OF THE COMMISSION OR THE ADVISORY BOARD, COMMISSION STAFF, AND THIRD–PARTY CONTRACTORS MAY NOT ACCEPT ANY GIFT OR DONATION OF SERVICES OR PROPERTY THAT INDICATE A POTENTIAL CONFLICT OF INTEREST OR HAVE THE APPEARANCE OF BIASING THE WORK OF THE COMMISSION.~~

~~21–2C–07.~~

~~(A) (1) A MANUFACTURER OF A PATENT–PROTECTED BRAND–NAME DRUG OR BIOLOGICAL SHALL NOTIFY THE COMMISSION:~~

~~(I) IF THE WHOLESALE ACQUISITION COST OF THE DRUG IS INCREASING BY MORE THAN 10% OR BY MORE THAN $10,000 DURING ANY 12–MONTH PERIOD; OR~~

~~(II) IF THE MANUFACTURER INTENDS TO INTRODUCE TO MARKET A BRAND–NAME DRUG THAT HAS A WHOLESALE ACQUISITION COST OF $30,000 PER CALENDAR YEAR OR PER COURSE OF TREATMENT.~~

~~(2) THE NOTICE PROVIDED BY THE MANUFACTURER UNDER PARAGRAPH (1) OF THIS SUBSECTION SHALL:~~

~~(I) BE PROVIDED IN WRITING AT LEAST 30 DAYS BEFORE THE PLANNED EFFECTIVE DATE OF THE INCREASE OR THE INTRODUCTION OF THE DRUG TO MARKET; AND~~

~~(II) INCLUDE A JUSTIFICATION FOR THE PROPOSED PRICING THAT INCLUDES ANY DOCUMENTS AND RESEARCH RELATED TO THE MANUFACTURER'S SELECTION OF THE INTRODUCTORY PRICE OR PRICE INCREASE, INCLUDING LIFE–CYCLE MANAGEMENT, NET AVERAGE PRICE TO THE STATE, MARKET COMPETITION AND CONTEXT, PROJECTED REVENUE, AND THE ESTIMATED VALUE OR COST–EFFECTIVENESS OF THE PRODUCT, IF AVAILABLE.~~

~~(B) (1) THE COMMISSION, IN CONSULTATION WITH STAKEHOLDERS AND EXPERTS, SHALL ESTABLISH A THRESHOLD FOR MANUFACTURER REPORTING OF BRAND PRESCRIPTION DRUGS, INCLUDING BIOLOGICS AND BIOSIMILARS.~~

~~(2) THE REPORTING THRESHOLD ESTABLISHED BY THE COMMISSION UNDER PARAGRAPH (1) OF THIS SUBSECTION SHALL APPLY TO BRAND NAME PRESCRIPTION DRUGS THAT ARE NOT REPORTED UNDER SUBSECTION (A) OF THIS SECTION BUT THAT IMPOSE COSTS ON THE STATE HEALTH CARE SYSTEM THAT CREATE SIGNIFICANT CHALLENGES TO AFFORDABILITY.~~

~~(C) (1) A MANUFACTURER OF A GENERIC OR OFF–PATENT SOLE SOURCE BRANDED PRODUCT DRUG SHALL NOTIFY THE COMMISSION IF THE MANUFACTURER IS INCREASING THE WHOLESALE ACQUISITION COST OF THE DRUG BY MORE THAN 25% OR BY MORE THAN $300 DURING ANY 12–MONTH PERIOD.~~

~~(2) THE NOTICE PROVIDED BY THE MANUFACTURER UNDER PARAGRAPH (1) OF THIS SUBSECTION SHALL:~~

~~(I) BE PROVIDED IN WRITING AT LEAST 30 DAYS BEFORE THE PLANNED EFFECTIVE DATE OF THE INCREASE OR THE INTRODUCTION OF THE DRUG TO MARKET; AND~~

~~(II) INCLUDE A JUSTIFICATION FOR THE PROPOSED PRICING THAT INCLUDES ANY DOCUMENTS AND RESEARCH RELATED TO THE MANUFACTURER'S SELECTION OF THE PRICE INCREASE, INCLUDING LIFE–CYCLE MANAGEMENT, NET AVERAGE PRICE TO THE STATE, MARKET COMPETITION AND CONTEXT, PROJECTED REVENUE, AND THE ESTIMATED VALUE OR COST EFFECTIVENESS OF THE PRODUCT, IF AVAILABLE.~~

~~(D) (1) THE COMMISSION, IN CONSULTATION WITH STAKEHOLDERS AND EXPERTS, SHALL ESTABLISH A THRESHOLD FOR MANUFACTURER REPORTING OF GENERIC AND OFF–PATENT SOLE SOURCE BRANDED PRESCRIPTION DRUGS.~~

~~(2) THE REPORTING THRESHOLD ESTABLISHED BY THE COMMISSION UNDER PARAGRAPH (1) OF THIS SUBSECTION SHALL APPLY TO GENERIC AND OFF–PATENT SOLE SOURCE BRANDED PRESCRIPTION DRUGS THAT ARE NOT REPORTED UNDER SUBSECTION (A) OF THIS SECTION BUT THAT IMPOSE COSTS ON THE STATE HEALTH CARE SYSTEM THAT CREATE SIGNIFICANT CHALLENGES TO AFFORDABILITY.~~

~~(E) (1) TO THE EXTENT FEASIBLE AND PRACTICABLE, THE COMMISSION SHALL ACCESS MANUFACTURER JUSTIFICATION INFORMATION MADE PUBLIC BY OTHER STATES.~~

~~(2) IF MANUFACTURER JUSTIFICATION INFORMATION IS NOT AVAILABLE FROM OTHER STATE SOURCES, THE COMMISSION SHALL REQUIRE A MANUFACTURER TO SUBMIT TO THE COMMISSION ANY DOCUMENTS AND RESEARCH RELATED TO THE MANUFACTURER'S SELECTION OF THE INTRODUCTORY PRICE OR PRICE INCREASE, 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 PRODUCT, IF AVAILABLE.~~

~~(F) (1) THE COMMISSION SHALL INFORM THE PUBLIC ABOUT THE REPORTS PROVIDED UNDER THIS SECTION.~~

~~(2) THE COMMISSION SHALL ALLOW THE PUBLIC TO REQUEST COMMISSION REVIEW OF THE COST OF ANY PRESCRIPTION DRUG REPORTED UNDER THIS SECTION.~~

~~(3) (I) THE CHAIR OF THE COMMISSION SHALL REVIEW ANY PUBLIC REQUEST MADE UNDER PARAGRAPH (2) OF THIS SUBSECTION TO DETERMINE WHETHER TO REVIEW THE COST OF THE PRESCRIPTION DRUG.~~

~~(II) THE CHAIR MAY INITIATE A REVIEW OF THE COST OF A PRESCRIPTION DRUG REPORTED UNDER THIS SECTION IN THE ABSENCE OF A PUBLIC REQUEST.~~

~~(III) IF THERE IS NOT CONSENSUS AMONG THE MEMBERS OF THE COMMISSION ON A DECISION BY THE CHAIR WHETHER OR NOT TO REVIEW A PRESCRIPTION DRUG, THE MEMBERS OF THE COMMISSION MAY REQUEST A VOTE ON WHETHER OR NOT TO REVIEW THE PRESCRIPTION DRUG.~~

~~(G) (1) IF THE COMMISSION CONDUCTS A REVIEW OF THE COST OF A PRESCRIPTION DRUG, THE REVIEW SHALL DETERMINE IF A UTILIZATION OF THE DRUG THAT IS FULLY CONSISTENT WITH THE FEDERAL FOOD AND DRUG ADMINISTRATION LABEL HAS LED OR WILL LEAD TO EXCESS COSTS FOR HEALTH CARE SYSTEMS IN THE STATE.~~

~~(2) THE COMMISSION MAY CONSIDER THE FOLLOWING FACTORS IN DETERMINING COST AND EXCESS COSTS:~~

~~(I) THE PRICE AT WHICH THE PRESCRIPTION DRUG HAS BEEN OR WILL BE SOLD IN THE STATE;~~

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

~~(III) THE TOTAL AMOUNT OF THE CONCESSION, DISCOUNT, OR REBATE THE MANUFACTURER PROVIDES TO EACH PHARMACY BENEFIT MANAGER OPERATING IN THE STATE FOR THE PRESCRIPTION DRUG UNDER REVIEW, EXPRESSED AS A PERCENT OF THE WHOLESALE ACQUISITION COST;~~

~~(IV) THE PRICE AT WHICH THERAPEUTIC ALTERNATIVES HAVE BEEN OR WILL BE SOLD IN THE STATE;~~

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

~~(VI) THE COST TO PAYORS BASED ON PATIENT ACCESS CONSISTENT WITH FEDERAL FOOD AND DRUG ADMINISTRATION LABELED INDICATIONS;~~

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

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

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

~~(X) ANY OTHER FACTOR AS DETERMINED BY THE COMMISSION IN REGULATIONS ADOPTED BY THE COMMISSION.~~

~~(3) IF THE COMMISSION IS UNABLE TO DETERMINE WHETHER A PRESCRIPTION DRUG PRODUCT WILL PRODUCE OR HAS PRODUCED EXCESS COSTS USING THE FACTORS LISTED IN PARAGRAPH (2) OF THIS SUBSECTION, THE COMMISSION MAY CONSIDER THE FOLLOWING FACTORS:~~

~~(I) MANUFACTURER RESEARCH AND DEVELOPMENT COSTS, AS INDICATED ON THE MANUFACTURER'S FEDERAL TAX FILING 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 COMMISSION CONSIDERS RELEVANT; AND~~

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

~~(II) (1) IF THE COMMISSION FINDS THAT THE SPENDING ON A PRESCRIPTION DRUG PRODUCT REVIEWED UNDER THIS SECTION CREATES EXCESS COSTS FOR PAYORS AND CONSUMERS, THE COMMISSION SHALL ESTABLISH THE LEVEL OF REIMBURSEMENT THAT SHALL BE BILLED AND PAID AMONG:~~

~~(I) PAYORS AND PHARMACIES OR ADMINISTERING PROVIDERS;~~

~~(II) WHOLESALERS AND DISTRIBUTORS AND PHARMACIES OR ADMINISTERING PROVIDERS; AND~~

~~(III) PHARMACIES OR ADMINISTERING PROVIDERS AND UNINSURED CONSUMERS OR CONSUMERS IN A DEDUCTIBLE PERIOD.~~

~~(2) THE COMMISSION SHALL DETERMINE HOW EACH PARTICIPANT IN THE SUPPLY CHAIN OF THE PRESCRIPTION DRUG SHALL BE REMUNERATED.~~

~~(I) (1) SUBJECT TO PARAGRAPH (2) OF THIS SUBSECTION, ANY SUBMISSION MADE TO THE COMMISSION RELATED TO A DRUG COST REVIEW SHALL~~

~~BE MADE AVAILABLE TO THE PUBLIC WITH THE EXCEPTION OF INFORMATION DETERMINED BY THE COMMISSION TO BE PROPRIETARY.~~

~~(2) THE COMMISSION, AFTER PUBLIC NOTICE AND COMMENT, SHALL ESTABLISH THE STANDARDS FOR THE INFORMATION TO BE CONSIDERED PROPRIETARY UNDER PARAGRAPH (1) OF THIS SUBSECTION, INCLUDING STANDARDS FOR HEIGHTENED CONSIDERATION OF PROPRIETARY INFORMATION FOR SUBMISSIONS FOR A COST REVIEW OF A DRUG THAT IS NOT YET APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION.~~

~~**21–2C–08.**~~

~~(A) (1) THE NONCOMPLIANCE OF AN ENTITY TO BILL OR PAY THE REIMBURSEMENT RATES ESTABLISHED BY THE COMMISSION UNDER § 21–2C–07 OF THIS SUBTITLE SHALL BE REFERRED TO THE OFFICE OF THE ATTORNEY GENERAL.~~

~~(2) IT MAY NOT BE CONSIDERED NONCOMPLIANCE IF AN ENTITY OBTAINS PRICE CONCESSIONS FROM A MANUFACTURER THAT RESULT IN THE INSURER'S NET COST BEING LOWER THAN THE RATE ESTABLISHED BY THE COMMISSION.~~

~~(3) IF THE OFFICE OF THE ATTORNEY GENERAL FINDS THAT AN ENTITY WAS NONCOMPLIANT WITH COMMISSION REIMBURSEMENT REQUIREMENTS, THE OFFICE OF THE ATTORNEY GENERAL MAY PURSUE REMEDIES CONSISTENT WITH STATE LAW OR OTHER APPROPRIATE CRIMINAL LAWS IF THERE IS EVIDENCE OF INTENTIONAL PROFITEERING.~~

~~(4) THE OFFICE OF THE ATTORNEY GENERAL SHALL PROVIDE GUIDANCE TO STAKEHOLDERS CONCERNING ACTIVITIES THAT COULD BE CONSIDERED NONCOMPLIANT THAT ARE IN ADDITION TO BILLING AND PAYMENT WHERE DRUG COSTS EXCEED THE RATES ESTABLISHED BY THE COMMISSION.~~

~~(B) (1) THE FAILURE OF A MANUFACTURER TO NOTIFY THE COMMISSION AS REQUIRED UNDER § 21–2C–07 OF THIS SUBTITLE SHALL BE REFERRED TO THE OFFICE OF THE ATTORNEY GENERAL.~~

~~(2) 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 COMMISSION MAY REQUEST AN APPEAL OF THE DECISION WITHIN 30 DAYS AFTER THE FINDING OF THE COMMISSION.~~

~~(B) THE COMMISSION SHALL HEAR THE APPEAL AND MAKE A FINAL DECISION WITHIN 60 DAYS OF THE HEARING.~~

~~(C) ANY PERSON AGGRIEVED BY A FINAL DECISION OF THE COMMISSION MAY TAKE A DIRECT JUDICIAL APPEAL AS PROVIDED IN THE ADMINISTRATIVE PROCEDURE ACT.~~

~~21–22C–10.~~

~~(A) SUBJECT TO SUBSECTION (C) OF THIS SECTION, THE COMMISSION SHALL BE FUNDED BY AN ASSESSMENT ON EACH MANUFACTURER THAT IS REQUIRED TO PROVIDE NOTIFICATION TO THE COMMISSION UNDER § 21–2C–05 OF THIS SUBTITLE.~~

~~(B) THE COMMISSION SHALL DETERMINE THE AMOUNT OF THE ASSESSMENT REQUIRED UNDER SUBSECTION (A) OF THIS SECTION IN REGULATIONS.~~

~~(C) THE COMMISSION SHALL BE ESTABLISHED USING GENERAL FUNDS, WHICH SHALL BE REPAID TO THE STATE WITH THE ASSESSMENTS REQUIRED UNDER SUBSECTION (A) OF THIS SECTION.~~

~~21–2C–11.~~

~~THE COMMISSION SHALL MAKE AVAILABLE AN ANNUAL REPORT TO THE PUBLIC ON:~~

~~(1) PRESCRIPTION DRUG PRICE TRENDS;~~

~~(2) THE NUMBER OF MANUFACTURERS REQUIRED TO NOTIFY THE COMMISSION ABOUT DRUG PRICING AS REQUIRED UNDER § 21–2C–05 OF THIS SUBTITLE; AND~~

~~(3) THE NUMBER OF PRODUCTS THAT WERE SUBJECT TO COMMISSION REVIEW, INCLUDING THE RESULTS OF THE REVIEW AND THE NUMBER AND DISPOSITION OF APPEALS AND JUDICIAL REVIEWS OF COMMISSION DECISIONS.~~

~~SECTION 2. AND BE IT FURTHER ENACTED, That the terms of the initial members of the Drug Cost Review Commission shall expire as follows:~~

~~(1) two members in 2021;~~

~~(2) two members in 2022; and~~

~~(3) one member in 2023.~~

~~SECTION 3. AND BE IT FURTHER ENACTED, That the terms of the initial members of the Drug Cost Review Advisory Board shall expire as follows:~~

~~(1) four members in 2021;~~

~~(2) four members in 2022; and~~

~~(3) four members in 2023.~~

~~SECTION 4. 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 ~~5.~~ 2. AND BE IT FURTHER ENACTED, That this Act shall take effect ~~October 1, 2018~~ June 1, 2018. It shall remain effective for a period of 3 years and 1 month and, at the end of June 30, 2021, this Act, with no further action required by the General Assembly, shall be abrogated and of no further force and effect.

Approved:

_____

Governor.

_____

Speaker of the House of Delegates.

_____

President of the Senate.