SENATE BILL 437

J1 7lr1058
CF HB 666

By: **Senators Conway, Astle, Benson, Currie, Ferguson, Guzzone, Kelley, King, Lee, Madaleno, Manno, Mathias, McFadden, Muse, Nathan–Pulliam, Peters, Pinsky, Ramirez, Robinson, Rosapepe, Smith, Young, and Zucker**
Introduced and read first time: January 30, 2017
Assigned to: Finance

Committee Report: Favorable with amendments
Senate action: Adopted
Read second time: March 30, 2017

CHAPTER _____

AN ACT concerning

~~**Public Health – Expensive Drugs – Manufacturer Reporting and Drug Price Transparency Advisory Committee**~~
Maryland Health Insurance Coverage Protection Commission – Review of Drug Transparency and Notification Laws and Initiatives

FOR the purpose of requiring~~, on or before a certain date each year, the manufacturer of an expensive drug sold or offered for sale in the State to file with the Secretary of Health and Mental Hygiene a certain annual report; requiring that the annual report include certain categories of information; requiring the manufacturer to identify the information in a certain manner, provide certain documentation, have the information audited by a certain auditor, and include information for a certain year; providing that a certain annual report constitutes public information; prohibiting a custodian from denying inspection under the Public Information Act of a certain annual report or part of the report, or a certain notice or part of the notice; requiring the Secretary to post each annual report on a certain Web site; requiring the Secretary, in consultation with the Drug Price Transparency Advisory Committee, to adopt certain regulations; requiring the Secretary to publish a certain report on or before a certain date in certain years; requiring the Secretary to provide a copy of a certain report to the Governor and the General Assembly and post a copy on a certain Web site; establishing certain penalties; authorizing the Attorney General, under certain circumstances, to seek a certain court order in a certain court; requiring the Attorney General to serve a certain notice on a certain manufacturer at least a certain number of days before seeking the order; providing that the~~

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.

~~Attorney General is entitled to recover certain fees and costs under certain circumstances; establishing the Drug Price Transparency Advisory Committee; providing for the composition and chair of the Committee; prohibiting a member of the Committee from being affiliated with a manufacturer of an expensive drug or having any other conflict of interest relating to the duties of the Committee; specifying the duties of the Committee; requiring the Secretary to adopt certain regulations regarding the Committee; providing for the application of certain provisions of this Act; requiring a manufacturer of an expensive drug to file a notice with the Secretary before increasing a certain price or a certain cost by more than a certain percentage or amount during certain periods of time; requiring that the notice be filed at least a certain number of days before the increase takes effect, be in writing, and state certain information; requiring the Secretary, within a certain time period, to post the notice on a certain Web site and send certain electronic notice to certain purchasers and the State Board of Pharmacy; requiring the Secretary to establish a process through which a purchaser may request to receive a certain notice; defining certain terms~~ the Maryland Health Insurance Coverage Protection Commission to review certain prescription drug transparency and notification laws and initiatives and certain information for a certain purpose; authorizing the Commission to consider certain studies and receive input from certain experts for a certain purpose; making this Act subject to a certain contingency; and generally relating to ~~expensive~~ the Maryland Health Insurance Coverage Protection Commission and the pricing of prescription drugs.

~~BY adding to~~
~~Article – Health – General~~
~~Section 21–228, 21–229, and 21–229.1~~
~~Annotated Code of Maryland~~
~~(2015 Replacement Volume and 2016 Supplement)~~

~~Preamble~~

~~WHEREAS, Name brand and specialty drug costs rose over 12% in 2014, which is nearly double the cost increase in any other health care category; and~~

~~WHEREAS, Drug costs are a major cause of higher health insurance premiums each year; and~~

~~WHEREAS, In 2013, the U.S. health care system spent more than $80 billion on specialty drugs alone, which cost on average 37 times more than traditional drugs and represent 31% of total drug spending, and these costs are projected to increase to 44% of overall drug spending by 2017; and~~

~~WHEREAS, Certain drug manufacturers, exploiting insufficient competition in the market for certain essential generic drugs that had long been available to consumers at an affordable price, have in recent years imposed unconscionable price increases, impeding access to these drugs and putting patients and public health at risk; and~~

~~WHEREAS, Disclosure of drug development costs and marketing expenditures by drug manufacturers will foster transparency for consumers and public and private health insurers and create accountability on the part of drug manufacturers to deliver a fair return on public investment in their products; and~~

~~WHEREAS, Consumers and policymakers deserve more information on drug costs and cost increases to inform solutions that may help lower health care costs to consumers; and~~

~~WHEREAS, Requiring drug corporations to disclose the basis for the prices of their prescription drugs and to notify the public about substantial increases in prices would create accountability on the part of drug manufacturers and help to stem the increase in health care costs, which is harming individual consumers and the entire national economy; and~~

~~WHEREAS, The entire national health care system is at risk if drug costs are not stabilized; now, therefore,~~

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

~~**Article – Health – General**~~

~~**21–228.**~~

~~**(A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE MEANINGS INDICATED.**~~

~~**(2) "AVERAGE WHOLESALE PRICE" MEANS THE MEDI–SPAN AVERAGE WHOLESALE COST BASED ON THE ACTUAL ELEVEN–DIGIT NATIONAL DRUG CODE DISPENSED AS OF THE FILL DATE OF THE EXPENSIVE DRUG THAT:**~~

~~**(I) IS SUBMITTED BY THE DISPENSING PHARMACY; AND**~~

~~**(II) IS USED TO FILL THE PRESCRIPTION FOR THE EXPENSIVE DRUG.**~~

~~**(3) "EXPENSIVE DRUG" MEANS A PRESCRIPTION DRUG THAT:**~~

~~**(I) A MANUFACTURER MAKES AVAILABLE IN THE STATE; AND**~~

~~**(II) HAS A WHOLESALE ACQUISITION COST OF $2,500 OR MORE ANNUALLY OR PER COURSE OF TREATMENT.**~~

~~**(4) "FDA" MEANS THE FEDERAL FOOD AND DRUG ADMINISTRATION.**~~

~~(5) "MANUFACTURER" MEANS A PERSON THAT:~~

~~(I) IS AUTHORIZED BY THE FDA TO MARKET AND SELL AN EXPENSIVE DRUG IN THE UNITED STATES AS AN ORIGINATOR OR A LICENSEE; OR~~

~~(II) DIRECTLY OR INDIRECTLY, THROUGH ONE OR MORE INTERMEDIARIES, CONTROLS, IS CONTROLLED BY, OR IS UNDER COMMON CONTROL WITH A PERSON DESCRIBED IN ITEM (I) OF THIS PARAGRAPH.~~

~~(6) "THERAPEUTIC CLASS" MEANS A THERAPEUTIC CATEGORY OR CLASS OF DRUGS ESTABLISHED BY THE UNITED STATES PHARMACOPEIA THAT REFLECTS THERAPEUTIC USES OF DRUGS BASED ON THE INTERNATIONAL CLASSIFICATION OF DISEASES DIAGNOSTIC CODES.~~

~~(7) "WHOLESALE ACQUISITION COST" HAS THE MEANING STATED IN 42 U.S.C. § 1395W–3A.~~

~~(B) ON OR BEFORE MARCH 31 EACH YEAR, THE MANUFACTURER OF AN EXPENSIVE DRUG SOLD OR OFFERED FOR SALE IN THE STATE SHALL FILE WITH THE SECRETARY AN ANNUAL REPORT IN ACCORDANCE WITH THIS SECTION.~~

~~(C) THE ANNUAL REPORT SHALL INCLUDE THE FOLLOWING CATEGORIES OF INFORMATION REGARDING THE EXPENSIVE DRUG:~~

~~(1) RESEARCH AND DEVELOPMENT COSTS, INCLUDING THE TOTAL RESEARCH AND DEVELOPMENT COSTS FOR THE EXPENSIVE DRUG:~~

~~(I) INCURRED BY THE MANUFACTURER;~~

~~(II) INCURRED BY ANY PREDECESSOR TO THE MANUFACTURER;~~

~~(III) INCURRED BY ANY OTHER PERSON; AND~~

~~(IV) PAID BY OR THROUGH GOVERNMENTAL GRANTS OR OTHER GOVERNMENT FINANCIAL ASSISTANCE;~~

~~(2) INTELLECTUAL PROPERTY RIGHTS, APPROVALS, AND ASSOCIATED REGULATORY COSTS, INCLUDING:~~

~~(I) A LIST OF ALL PRODUCT AND PROCESS PATENTS AND ALL DATA MARKET AND EXCLUSIVITY AWARDED BY THE U.S. PATENT AND TRADEMARK OFFICE FOR THE EXPENSIVE DRUG;~~

~~(II) ALL REVERSE PAYMENT PATENT SETTLEMENTS INVOLVING THE EXPENSIVE DRUG; AND~~

~~(III) ALL REGULATORY COSTS PAID BY THE MANUFACTURER OR ITS PREDECESSORS IN OBTAINING THE RIGHTS AND APPROVALS, INCLUDING FDA USER AND FILING FEES AND FEES RELATED TO THE FILING OF PATENTS;~~

~~(3) MANUFACTURING, PRODUCTION, MARKETING, AND ADVERTISING COSTS, INCLUDING:~~

~~(I) THE TOTAL ANNUAL AND CUMULATIVE ITEMIZED COSTS FOR THE MANUFACTURER TO PRODUCE THE EXPENSIVE DRUG SINCE THE MANUFACTURER BEGAN PRODUCING THE EXPENSIVE DRUG;~~

~~(II) THE MANUFACTURER'S TOTAL DIRECT COSTS FOR MATERIALS, MANUFACTURING, AND ADMINISTRATION ATTRIBUTABLE TO THE EXPENSIVE DRUG; AND~~

~~(III) ALL MARKETING AND ADVERTISING COSTS FOR THE PROMOTION OF THE EXPENSIVE DRUG DIRECTLY TO CONSUMERS, INCLUDING:~~

~~1. COSTS ASSOCIATED WITH CONSUMER CO PAY COUPONS AND AMOUNTS REDEEMED; AND~~

~~2. MARKETING AND ADVERTISING COSTS FOR THE PROMOTION OF THE EXPENSIVE DRUG DIRECTLY OR INDIRECTLY TO PRESCRIBERS;~~

~~(4) PRICES OF THE EXPENSIVE DRUG AND RETURNS FROM SALES, INCLUDING:~~

~~(I) THE TOTAL REVENUES FROM SALES IN THE STATE AND IN THE UNITED STATES, LISTED SEPARATELY, FOR EACH OF THE IMMEDIATELY PRECEDING 5 CALENDAR YEARS; AND~~

~~(II) A CUMULATIVE MONTHLY HISTORY OF INCREASES IN THE AVERAGE WHOLESALE PRICE OR WHOLESALE ACQUISITION COST OF THE EXPENSIVE DRUG FOR THE IMMEDIATELY PRECEDING 5 CALENDAR YEARS, INCLUDING EACH MONTH IN WHICH AN INCREASE IN AVERAGE WHOLESALE PRICE OR WHOLESALE ACQUISITION COST TOOK EFFECT;~~

~~(5) THE MANUFACTURER'S FEDERAL, STATE, AND LOCAL INCOME TAX RATES, GOVERNMENTAL BENEFITS, AND CREDITS, INCLUDING:~~

~~(I) THE FEDERAL, STATE, AND ANY APPLICABLE LOCAL INCOME TAX RATE PAID BY THE MANUFACTURER;~~

~~(II) THE TOTAL AMOUNT PAID BY ANY PERSON OTHER THAN THE MANUFACTURER FOR MATERIALS, MANUFACTURING, MARKETING, ADVERTISING, ADMINISTRATION, AND OTHER COSTS ATTRIBUTABLE TO THE EXPENSIVE DRUG, INCLUDING ANY FEDERAL, STATE, AND LOCAL TAX CREDITS OR SUBSIDIES, TAX DEDUCTIONS, GRANTS, OR OTHER SUPPORT RECEIVED OR DEFERRED; AND~~

~~(III) ALL INCOME FROM ANY SOURCE FROM ANY OF THE FOLLOWING ACTIVITIES UNDERTAKEN IN A FOREIGN COUNTRY BY OR ON BEHALF OF THE MANUFACTURER OF AN EXPENSIVE DRUG:~~

~~1. RESEARCHING, DEVELOPING, MANUFACTURING, OR PRODUCING THE EXPENSIVE DRUG;~~

~~2. THE SALE, EXCHANGE, OR OTHER DISPOSITION OF THE EXPENSIVE DRUG; OR~~

~~3. THE LEASE, RENTAL, OR LICENSING OF THE EXPENSIVE DRUG;~~

~~(6) FINANCIAL ASSISTANCE PROVIDED TO PATIENTS, INCLUDING:~~

~~(I) THE TOTAL AMOUNT OF FINANCIAL ASSISTANCE TO PATIENTS THAT THE MANUFACTURER HAS PROVIDED FOR THE EXPENSIVE DRUG, FOR EACH OF THE IMMEDIATELY PRECEDING 5 CALENDAR YEARS, INCLUDING:~~

~~1. DISCOUNTS;~~

~~2. REBATES AND PATIENT PRESCRIPTION ASSISTANCE PROGRAMS;~~

~~3. CO–PAY ASSISTANCE COSTS; AND~~

~~4. TOTAL DONATIONS TO PATIENT ASSISTANCE NONPROFITS AND THE RELATED TAX DEDUCTIONS; AND~~

~~(II) THE NUMBER OF PATIENTS WHO HAVE BENEFITED FROM THE MANUFACTURER'S FINANCIAL ASSISTANCE FOR EACH OF THE IMMEDIATELY PRECEDING 5 CALENDAR YEARS;~~

~~(7) THE COMPARATIVE EFFECTIVENESS OF THE EXPENSIVE DRUG, INCLUDING:~~

~~(I) THE THERAPEUTIC CLASS OF THE EXPENSIVE DRUG;~~

~~(II) THE NAMES OF ANY OTHER BRAND NAME OR GENERIC DRUGS APPROVED BY THE FDA IN THE SAME THERAPEUTIC CLASS; AND~~

~~(III) ANY CLINICAL OR PHARMACOECONOMIC EVIDENCE INDICATING THE EXPENSIVE DRUG'S IMPROVED EFFICACY COMPARED TO ALL OTHER BRAND NAME OR GENERIC DRUGS APPROVED BY THE FDA IN THE SAME THERAPEUTIC CLASS; AND~~

~~(8) ANY OTHER CATEGORY OF INFORMATION REQUIRED TO BE INCLUDED UNDER REGULATIONS ADOPTED UNDER SUBSECTION (F) OF THIS SECTION.~~

~~(D) THE MANUFACTURER SHALL:~~

~~(1) SEPARATELY IDENTIFY BY LINE ITEM THE INFORMATION INCLUDED IN THE ANNUAL REPORT TO THE MAXIMUM EXTENT POSSIBLE TO PROMOTE PUBLIC TRANSPARENCY AND UNDERSTANDING OF THE INFORMATION;~~

~~(2) PROVIDE DOCUMENTATION FOR THE INFORMATION INCLUDED IN THE ANNUAL REPORT;~~

~~(3) HAVE THE INFORMATION IN THE ANNUAL REPORT AUDITED BY AN INDEPENDENT THIRD-PARTY AUDITOR BEFORE THE REPORT IS FILED WITH THE SECRETARY; AND~~

~~(4) INCLUDE INFORMATION FOR THE IMMEDIATELY PRECEDING CALENDAR YEAR, UNLESS ANOTHER REPORTING PERIOD IS REQUIRED UNDER SUBSECTION (C) OF THIS SECTION.~~

~~(E) (1) AN ANNUAL REPORT FILED UNDER SUBSECTION (B) OF THIS SECTION SHALL CONSTITUTE PUBLIC INFORMATION.~~

~~(2) A CUSTODIAN MAY NOT DENY INSPECTION UNDER THE PUBLIC INFORMATION ACT OF AN ANNUAL REPORT FILED UNDER SUBSECTION (B) OF THIS SECTION, OR ANY PART OF THE REPORT.~~

~~(3) THE SECRETARY SHALL POST EACH ANNUAL REPORT FILED UNDER SUBSECTION (B) OF THIS SECTION ON THE DEPARTMENT'S WEB SITE.~~

~~(F) (1) THE SECRETARY, IN CONSULTATION WITH THE DRUG PRICE TRANSPARENCY ADVISORY COMMITTEE ESTABLISHED UNDER § 21–229(B) OF THIS SUBTITLE, SHALL ADOPT REGULATIONS TO IMPLEMENT THIS SECTION.~~

~~(2) THE REGULATIONS SHALL:~~

~~(I) FACILITATE PUBLIC TRANSPARENCY REGARDING:~~

~~1. THE PRICING OF EXPENSIVE DRUGS;~~

~~2. THE RETURN REALIZED BY MANUFACTURERS FROM THE SALE OF EXPENSIVE DRUGS; AND~~

~~3. THE RETURN ON PUBLIC INVESTMENT IN THE DEVELOPMENT OF EXPENSIVE DRUGS MADE THROUGH FEDERAL, STATE, OR LOCAL GRANTS OR OTHER GOVERNMENT FINANCIAL ASSISTANCE;~~

~~(II) IDENTIFY ANY ADDITIONAL INFORMATION WITHIN EACH OF THE CATEGORIES LISTED IN SUBSECTION (C) OF THIS SECTION THAT THE MANUFACTURER MUST INCLUDE IN AN ANNUAL REPORT; AND~~

~~(III) INCLUDE A UNIFORM REPORTING FORM THAT THE MANUFACTURER MUST USE TO FACILITATE:~~

~~1. THE DISCLOSURE OF THE INFORMATION REQUIRED TO BE REPORTED UNDER SUBSECTION (C) OF THIS SECTION; AND~~

~~2. THE SECRETARY'S PREPARATION OF THE REPORT REQUIRED UNDER SUBSECTION (G) OF THIS SECTION.~~

~~(G) (1) ON OR BEFORE DECEMBER 31, 2018, AND ON OR BEFORE DECEMBER 31 EACH YEAR THEREAFTER, THE SECRETARY SHALL PUBLISH A REPORT THAT SUMMARIZES THE REPORTS FILED BY MANUFACTURERS UNDER SUBSECTION (B) OF THIS SECTION SINCE THE LAST REPORT PUBLISHED BY THE SECRETARY.~~

~~(2) THE SECRETARY SHALL:~~

~~(I) PROVIDE A COPY OF EACH REPORT PUBLISHED UNDER PARAGRAPH (1) OF THIS SUBSECTION TO THE GOVERNOR AND, IN ACCORDANCE WITH § 2–1246 OF THE STATE GOVERNMENT ARTICLE, THE GENERAL ASSEMBLY; AND~~

~~(II) POST A COPY OF THE REPORT ON THE DEPARTMENT'S WEB SITE.~~

~~(II) IF A MANUFACTURER FAILS TO FILE AN ANNUAL REPORT AS REQUIRED UNDER SUBSECTION (B) OF THIS SECTION OR FILES AN INACCURATE ANNUAL REPORT, THE SECRETARY SHALL IMPOSE A CIVIL PENALTY NOT TO EXCEED $10,000 FOR EACH DAY THE VIOLATION CONTINUES.~~

~~(I) (1) IF A MANUFACTURER FAILS TO FILE AN ANNUAL REPORT AS REQUIRED UNDER SUBSECTION (B) OF THIS SECTION, THE ATTORNEY GENERAL MAY SEEK A COURT ORDER IN A COURT OF COMPETENT JURISDICTION REQUIRING THE MANUFACTURER TO FILE THE REQUIRED REPORT.~~

~~(2) THE ATTORNEY GENERAL SHALL SERVE NOTICE ON THE MANUFACTURER OF THE INTENT TO SEEK AN ORDER UNDER PARAGRAPH (1) OF THIS SUBSECTION AT LEAST 7 DAYS BEFORE SEEKING THE ORDER.~~

~~(3) IF THE ATTORNEY GENERAL IS GRANTED AN ORDER REQUIRING THE MANUFACTURER TO FILE A REQUIRED REPORT, THE ATTORNEY GENERAL SHALL BE ENTITLED TO RECOVER REASONABLE ATTORNEY'S FEES AND COSTS.~~

~~21–229.~~

~~(A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE MEANINGS INDICATED.~~

~~(2) "ADVISORY COMMITTEE" MEANS THE DRUG PRICE TRANSPARENCY ADVISORY COMMITTEE.~~

~~(3) "MANUFACTURER" HAS THE MEANING STATED IN § 21–228 OF THIS SUBTITLE.~~

~~(B) THERE IS A DRUG PRICE TRANSPARENCY ADVISORY COMMITTEE.~~

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

~~(1) THE SECRETARY, OR THE SECRETARY'S DESIGNEE; AND~~

~~(2) THE FOLLOWING MEMBERS, APPOINTED BY THE SECRETARY:~~

~~(I) TWO ACADEMIC PUBLIC HEALTH RESEARCHERS;~~

~~(II) ONE ECONOMIST;~~

~~(III) ONE CERTIFIED PUBLIC ACCOUNTANT;~~

~~(IV) ONE LICENSED PHYSICIAN WHO PRACTICES IN THE STATE;~~

~~(V) ONE LICENSED PHARMACIST WHO PRACTICES IN THE STATE; AND~~

~~(VI) TWO CONSUMER REPRESENTATIVES.~~

~~(D) A MEMBER OF THE ADVISORY COMMITTEE MAY NOT BE AFFILIATED WITH A MANUFACTURER OR HAVE ANY OTHER CONFLICT OF INTEREST RELATING TO THE DUTIES OF THE ADVISORY COMMITTEE.~~

~~(E) THE ADVISORY COMMITTEE SHALL ADVISE THE SECRETARY REGARDING:~~

~~(1) THE DEVELOPMENT OF THE REGULATIONS REQUIRED UNDER § 21–228(F) OF THIS SUBTITLE;~~

~~(2) THE REVIEW OF THE ANNUAL REPORTS FILED BY MANUFACTURERS UNDER § 21–228(B) OF THIS SUBTITLE; AND~~

~~(3) THE PREPARATION OF THE REPORTS THE SECRETARY IS REQUIRED TO PUBLISH UNDER § 21–228(G) OF THIS SUBTITLE.~~

~~(F) THE SECRETARY, OR THE SECRETARY'S DESIGNEE, SHALL CHAIR THE ADVISORY COMMITTEE.~~

~~(G) (1) THE SECRETARY SHALL ADOPT REGULATIONS TO CARRY OUT THIS SECTION.~~

~~(2) THE REGULATIONS ADOPTED UNDER PARAGRAPH (1) OF THIS SUBSECTION SHALL INCLUDE REGULATIONS GOVERNING:~~

~~(I) THE MINIMUM NUMBER OF TIMES THE ADVISORY COMMITTEE MUST MEET EACH YEAR;~~

~~(II) ANY COMPENSATION FOR AND REIMBURSEMENT OF EXPENSES INCURRED BY ADVISORY COMMITTEE MEMBERS; AND~~

~~(III) THE TERMS OF ADVISORY COMMITTEE MEMBERS.~~

~~21–229.1.~~

~~(A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE MEANINGS INDICATED.~~

~~(2) "AVERAGE WHOLESALE PRICE" HAS THE MEANING STATED IN § 21–228 OF THIS SUBTITLE.~~

~~(3) "EXPENSIVE DRUG" HAS THE MEANING STATED IN § 21–228 OF THIS SUBTITLE.~~

~~(4) "MANUFACTURER" HAS THE MEANING STATED IN § 21–228 OF THIS SUBTITLE.~~

~~(5) "PURCHASER" MEANS:~~

~~(I) THE STATE, INCLUDING:~~

~~1. THE STATE EMPLOYEE AND RETIREE HEALTH AND WELFARE BENEFITS PROGRAM;~~

~~2. THE MARYLAND MEDICAL ASSISTANCE PROGRAM;~~

~~3. THE MARYLAND PHARMACY ASSISTANCE PRESCRIPTION DRUG PROGRAM;~~

~~4. THE MARYLAND MEDBANK PROGRAM;~~

~~5. THE MEDICARE OPTION PRESCRIPTION DRUG PROGRAM; AND~~

~~6. THE MARYLAND CHILDREN'S HEALTH PROGRAM;~~

~~(II) A LOCAL GOVERNMENT;~~

~~(III) A MANAGED CARE ORGANIZATION AS DEFINED IN § 15–101 OF THIS ARTICLE;~~

~~(IV) AN AUTHORIZED INSURER THAT PROVIDES HEALTH INSURANCE IN THE STATE;~~

~~(V) A NONPROFIT HEALTH SERVICE PLAN;~~

~~(VI) A HEALTH MAINTENANCE ORGANIZATION;~~

~~(VII) A DENTAL PLAN ORGANIZATION;~~

~~(VIII) A PHARMACY BENEFITS MANAGER REGULATED UNDER TITLE 15, SUBTITLE 16 OF THE INSURANCE ARTICLE; AND~~

~~(IX) ANY OTHER PERSON THAT PROVIDES HEALTH BENEFIT PLANS SUBJECT TO REGULATION BY THE STATE.~~

~~(6) "WHOLESALE ACQUISITION COST" HAS THE MEANING STATED IN § 21–228 OF THIS SUBTITLE.~~

~~(B) THIS SECTION APPLIES ONLY TO A MANUFACTURER OF AN EXPENSIVE DRUG THAT IS SOLD OR OFFERED FOR SALE IN THE STATE.~~

~~(C) A MANUFACTURER OF AN EXPENSIVE DRUG SHALL FILE A NOTICE WITH THE SECRETARY BEFORE INCREASING THE AVERAGE WHOLESALE PRICE OR WHOLESALE ACQUISITION COST OF THE EXPENSIVE DRUG BY MORE THAN:~~

~~(1) 10% OR $2,500, WHICHEVER IS LESS, DURING A 12–MONTH PERIOD; OR~~

~~(2) 15% CUMULATIVELY DURING ANY 24–MONTH PERIOD.~~

~~(D) THE NOTICE REQUIRED UNDER SUBSECTION (C) OF THIS SECTION SHALL:~~

~~(1) BE FILED AT LEAST 60 DAYS BEFORE THE INCREASE TAKES EFFECT;~~

~~(2) BE IN WRITING; AND~~

~~(3) STATE:~~

~~(I) THE JUSTIFICATION FOR THE PRICE INCREASE;~~

~~(II) THE MARKETING BUDGET FOR THE EXPENSIVE DRUG IN THE IMMEDIATELY PRECEDING CALENDAR YEAR;~~

~~(III) IF THE EXPENSIVE DRUG WAS NOT DEVELOPED BY THE MANUFACTURER, THE DATE THE EXPENSIVE DRUG WAS ACQUIRED BY THE MANUFACTURER AND THE PRICE OF THE ACQUISITION; AND~~

~~(IV) THE HISTORY OF ALL PRICE INCREASES FOR THE EXPENSIVE DRUG THAT TOOK EFFECT DURING THE IMMEDIATELY PRECEDING 5 CALENDAR YEARS.~~

~~(E) (1) WITHIN 15 DAYS AFTER A NOTICE IS FILED UNDER SUBSECTION (C) OF THIS SECTION, THE SECRETARY SHALL:~~

~~(I) POST THE NOTICE ON THE DEPARTMENT'S WEB SITE; AND~~

~~(II) SEND ELECTRONIC NOTICE OF THE FILING TO:~~

~~1. PURCHASERS THAT HAVE REQUESTED TO RECEIVE NOTIFICATION; AND~~

~~2. THE STATE BOARD OF PHARMACY.~~

~~(2) A CUSTODIAN MAY NOT DENY INSPECTION UNDER THE PUBLIC INFORMATION ACT OF A NOTICE, OR ANY PART OF A NOTICE, FILED UNDER SUBSECTION (C) OF THIS SECTION.~~

~~(F) THE SECRETARY SHALL ESTABLISH A PROCESS THROUGH WHICH A PURCHASER MAY REQUEST TO RECEIVE NOTICE OF FILINGS MADE UNDER SUBSECTION (C) OF THIS SECTION.~~

~~(G) IF A MANUFACTURER FAILS TO FILE A NOTICE AS REQUIRED UNDER SUBSECTION (C) OF THIS SECTION OR FILES AN INACCURATE NOTICE, THE SECRETARY SHALL IMPOSE A CIVIL PENALTY NOT TO EXCEED $10,000 FOR EACH DAY THE VIOLATION CONTINUES.~~

(a) The Maryland Health Insurance Coverage Protection Commission shall review:

(1) prescription drug price transparency and notification laws and initiatives adopted and implemented in other states; and

(2) information on prescription drug pricing reported by prescription drug manufacturers and other entities required to report information under prescription drug transparency laws and initiatives adopted and implemented in other states.

(b) (1) The Commission shall review the laws, initiatives, and information under subsection (a) of this section to assess proposals for the adoption and implementation of laws or other initiatives in the State relating to prescription drug price transparency and notification.

(2) The Commission may consider studies and receive input from experts on prescription drug pricing to perform its review under this section.

(c) The Commission shall include any findings and recommendations from its review of the laws, initiatives, and information under subsection (a) of this section in the annual report of the Commission submitted to the Governor and the General Assembly.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect ~~October~~ June 1, 2017, contingent on the taking effect of Chapter __ (S.B. 571/H.B. 909) of the Acts of the General Assembly of 2017, and if Chapter __ (S.B. 571/H.B. 909) does not become effective, this Act shall be null and void without the necessity of further action by the General Assembly.

Approved:

_____

Governor.

_____

President of the Senate.

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Speaker of the House of Delegates.