

HOUSE BILL 768

J1, C3

(9lr0936)

ENROLLED BILL

— Health and Government Operations/Finance —

Introduced by **Delegates Pena–Melnyk, D. Barnes, Acevero, Anderson, Atterbeary, Bagnall, B. Barnes, Barron, Bartlett, Barve, Boyce, Bridges, Brooks, Cain, Cardin, Carey, Carr, Cassilly, Chang, Charkoudian, Charles, Ciliberti, Clippinger, Conaway, Corderman, Crosby, Crutchfield, D.M. Davis, D.E. Davis, Dumais, Ebersole, Feldmark, Fennell, W. Fisher, Fraser–Hidalgo, Gaines, Ghrist, Gilchrist, Glenn, Guyton, Harrison, Haynes, Healey, Hettleman, Hill, Holmes, Impallaria, Ivey, Jackson, Jalisi, Johnson, Jones, Kaiser, Kelly, Kerr, Korman, Krimm, Lafferty, Lehman, J. Lewis, R. Lewis, Lierman, Lisanti, Lopez, Love, Luedtke, McIntosh, Metzgar, Moon, Mosby, Palakovich Carr, Patterson, Proctor, Qi, Queen, Reilly, Reznik, Rogers, Rosenberg, Sample–Hughes, Shetty, Smith, Solomon, Stein, Stewart, Sydnor, Terrasa, Turner, Valderrama, Valentino–Smith, Walker, Washington, C. Watson, R. Watson, Wilkins, Wilson, K. Young, ~~and P. Young~~ P. Young, Pendergrass, Bhandari, and Cullison**

Read and Examined by Proofreaders:

Proofreader.

Proofreader.

Sealed with the Great Seal and presented to the Governor, for his approval this _____ day of _____ at _____ o'clock, _____ M.

Speaker.

CHAPTER _____

1 AN ACT concerning

2 **Health – Prescription Drug Affordability Board**

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.

Italics indicate opposite chamber/conference committee amendments.



1 FOR the purpose of establishing the Prescription Drug Affordability Board as an
2 independent unit of State government; providing that the exercise by the Board of
3 its authority under this Act is an essential governmental function; providing for the
4 purpose of the Board; providing for the membership, terms, compensation, and chair
5 of the Board; requiring certain conflicts of interest to be disclosed and considered
6 when appointing members to the Board; specifying the terms of the initial members
7 and alternate members of the Board; requiring the chair of the Board to hire certain
8 staff and develop a certain budget and plan to be submitted to the Board for approval;
9 requiring that the staff of the Board receive a certain salary; requiring the Board to
10 meet in a certain manner and with a certain frequency with certain exceptions;
11 requiring the Board to provide certain public notice of each Board meeting and to
12 make certain materials available to the public in a certain manner; requiring the
13 Board to provide the public with the opportunity to provide certain comments;
14 authorizing the Board to allow expert testimony under certain circumstances;
15 requiring the Board to access certain information for prescription drug products in a
16 certain manner; requiring certain actions by the Board to be made in open session;
17 providing that a majority of the members of the Board constitutes a quorum;
18 requiring members of the Board to recuse themselves from certain decisions under
19 certain circumstances; authorizing the Board to adopt certain regulations and enter
20 into certain contracts; providing that certain third parties may not use certain
21 information except under certain circumstances; providing for the application of
22 certain procurement law to the Board; establishing the Prescription Drug
23 Affordability Stakeholder Council; providing for the purpose of the Stakeholder
24 Council; providing for the membership of the Stakeholder Council; specifying the
25 terms of the initial members of the Stakeholder Council; requiring the Board to
26 appoint certain chairs for the Stakeholder Council; prohibiting a member of the
27 Stakeholder Council from receiving certain compensation, but authorizing the
28 reimbursement of certain expenses; requiring the disclosure of certain conflicts of
29 interest within a certain time frame and in a certain manner; prohibiting certain
30 persons from accepting certain gifts or donations; providing for the construction of
31 certain provisions of this Act; requiring the Board in consultation with the
32 Stakeholder Council to ~~make certain determinations and adopt certain regulations~~
33 conduct a certain study and submit a certain report to certain committees of the
34 General Assembly on or before a certain date; requiring the Board to *collect and*
35 *review certain information, identify certain states, and initiate a certain process on*
36 *or before a certain date; requiring the Board, in consultation with the Stakeholder*
37 *Council, to adopt certain regulations*; requiring the Board to *use certain information*
38 *to identify certain prescription drug products with certain costs*; requiring the Board
39 to determine in a certain manner whether to conduct a certain review for certain
40 identified products; requiring the Board to request certain information from ~~a~~
41 ~~manufacturer~~ certain entities under certain circumstances; providing that
42 information to conduct a certain cost review includes certain documents and
43 research; providing that failure of ~~a manufacturer~~ certain entities to provide the
44 Board with certain information does not affect certain Board authority; requiring
45 that a certain review determine if certain utilization of a prescription drug product
46 has led or will lead to certain challenges; requiring the Board to consider certain

1 factors in making a certain determination on whether a certain drug product has led
2 or will lead to certain challenges; authorizing the Board to consider certain
3 additional factors if the Board is unable to make a certain determination; ~~requiring~~
4 ~~the Board to recommend or establish set certain upper payment limits after~~
5 ~~considering certain factors; requiring the Board to work with certain stakeholders to~~
6 ~~identify certain methodologies and establish certain data sources on or before a~~
7 ~~certain date; providing for the application of certain provisions of this Act; requiring~~
8 ~~the Board to consider certain information and recommend and publicize certain~~
9 ~~upper payment limits on or before a certain date; requiring the Board to establish~~
10 ~~set certain upper payment limits for certain prescription drug products on or after a~~
11 ~~certain date; *prohibiting certain materials from being made available to the public;*~~
12 ~~*authorizing only certain Board members and staff to access certain information;*~~
13 ~~*providing that certain provisions of law regarding trade secrets apply to certain*~~
14 ~~*information obtained under certain provisions of this Act; requiring the Board to draft*~~
15 ~~*a certain plan of action under certain circumstances; requiring that certain criteria*~~
16 ~~*include consideration of certain factors; requiring that a certain process prohibit the*~~
17 ~~*application of upper payment limits to certain prescription drug products, and require*~~
18 ~~*the Board to monitor certain prescriptions drug products and reconsider or suspend*~~
19 ~~*certain upper payment limits; requiring the Board, under certain circumstances, to*~~
20 ~~*submit a certain plan to the Legislative Policy Committee of the General Assembly for*~~
21 ~~*its approval on or before a certain date; providing that the Committee has a certain*~~
22 ~~*number of days to approve a certain plan; requiring the Board to submit a certain*~~
23 ~~*plan to the Governor and the Attorney General if the Committee does not approve the*~~
24 ~~*plan; providing that the Governor and the Attorney General have a certain number of*~~
25 ~~*days to approve a certain plan; prohibiting the Board from setting upper payment*~~
26 ~~*limits unless a certain plan receives certain approval; authorizing the Board to set*~~
27 ~~*upper payment limits for certain prescription drug products on or after a certain date;*~~
28 ~~*requiring that certain information be subject to public inspection to the extent*~~
29 ~~*allowed under certain provisions of law; requiring the Board to monitor the*~~
30 ~~*availability of certain prescription drug products and reconsider upper payment*~~
31 ~~*limits under certain circumstances; prohibiting upper payment limits from applying*~~
32 ~~*to a prescription drug product while the prescription drug product is on a certain*~~
33 ~~*federal list; providing that certain information and data is considered *to be a trade**~~
34 ~~*secret and confidential and proprietary information and is not subject to disclosure*~~
35 ~~*under certain provisions of law; authorizing the Office of the Attorney General to*~~
36 ~~*pursue certain remedies; authorizing certain appeals and judicial review of certain*~~
37 ~~*Board decisions; establishing the Prescription Drug Affordability Fund; requiring*~~
38 ~~*the Board to be funded by a certain assessment; requiring the Board to assess and*~~
39 ~~*collect certain fees; requiring the State Treasurer to hold the Fund separately, and*~~
40 ~~*the Comptroller to account for the Fund; providing that the Fund is not subject to*~~
41 ~~*certain provisions of law but is subject to certain audit by the Office of Legislative*~~
42 ~~*Audits; requiring the Board to determine a certain funding source and submit a*~~
43 ~~*certain recommendation to certain committees of the General Assembly on or before*~~
44 ~~*a certain date; requiring the Board to be funded in a certain manner; requiring the*~~
45 ~~*Board to submit certain reports to certain committees of the General Assembly and*~~
46 ~~*to the General Assembly on or before certain dates; requiring the Health Services*~~
47 ~~*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; requiring the State Designated Health Information Exchange Board jointly to conduct a study with the Board on providing certain data and report certain findings and recommendations to the General Assembly on or before a certain date; defining certain terms; providing for the application of this Act; subjecting certain provisions of this Act to a certain contingency; providing for the termination of certain provisions of this Act under certain circumstances; 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~~ ~~21-2C-14~~ 21-2C-15 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

1 costs for consumers across wide market segments, leading to a rising, unsustainable strain
2 on State and commercial health plan budgets and lowering equitable access to
3 life-sustaining medications for Maryland residents; and

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

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

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

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

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

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

22 **Article – Health – General**

23 **SUBTITLE 2C. PRESCRIPTION DRUG AFFORDABILITY BOARD.**

24 **21-2C-01.**

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

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

30 (C) “BIOSIMILAR” MEANS A DRUG THAT IS PRODUCED OR DISTRIBUTED IN
31 ACCORDANCE WITH A BIOLOGICS LICENSE APPLICATION APPROVED UNDER 42
32 U.S.C. § 262(k)(3).

33 (D) “BOARD” MEANS THE PRESCRIPTION DRUG AFFORDABILITY BOARD.

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

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

6 (F) "GENERIC DRUG" MEANS:

7 (1) A RETAIL DRUG THAT IS MARKETED OR DISTRIBUTED IN
8 ACCORDANCE WITH AN ABBREVIATED NEW DRUG APPLICATION, APPROVED UNDER
9 21 U.S.C. § 355(J);

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

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

13 (G) "MANUFACTURER" MEANS AN ENTITY THAT:

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

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

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

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

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

25 21-2C-02.

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

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

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

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

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

10 **21-2C-03.**

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

13 **(I) ONE MEMBER APPOINTED BY THE GOVERNOR;**

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

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

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

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

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

27 **(I) ONE ALTERNATE MEMBER APPOINTED BY THE GOVERNOR;**

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

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

1 **(3) AT LEAST ONE MEMBER OF THE BOARD SHALL HAVE EXPERTISE**
 2 **IN:**

3 **(I) THE 340B PROGRAM UNDER THE FEDERAL PUBLIC**
 4 **HEALTH SERVICE ACT;**

5 **(II) THE STATE'S ALL-PAYER MODEL CONTRACT;**

6 **(III) HOW THE PROGRAM AND CONTRACT INTERACT; AND**

7 **(IV) HOW DECISIONS MADE BY THE BOARD WILL AFFECT THE**
 8 **MODEL AND CONTRACT.**

9 ~~**(3)**~~ **(4) A MEMBER OR AN ALTERNATE MEMBER MAY NOT BE AN**
 10 **EMPLOYEE OF, A BOARD MEMBER OF, OR A CONSULTANT TO A MANUFACTURER,**
 11 **PHARMACY BENEFITS MANAGER, HEALTH INSURANCE CARRIER, HEALTH**
 12 **MAINTENANCE ORGANIZATION, MANAGED CARE ORGANIZATION, OR WHOLESALE**
 13 **DISTRIBUTOR OR RELATED TRADE ASSOCIATION FOR MANUFACTURERS.**

14 ~~**(4)**~~ **(5) ANY CONFLICT OF INTEREST, INCLUDING WHETHER THE**
 15 **INDIVIDUAL HAS AN ASSOCIATION, INCLUDING A FINANCIAL OR PERSONAL**
 16 **ASSOCIATION, THAT HAS THE POTENTIAL TO BIAS OR HAS THE APPEARANCE OF**
 17 **BIASING AN INDIVIDUAL'S DECISION IN MATTERS RELATED TO THE BOARD OR THE**
 18 **CONDUCT OF THE BOARD'S ACTIVITIES, SHALL BE CONSIDERED AND DISCLOSED**
 19 **WHEN APPOINTING MEMBERS AND ALTERNATE MEMBERS TO THE BOARD.**

20 ~~**(5)**~~ **(6) TO THE EXTENT PRACTICABLE AND CONSISTENT WITH**
 21 **FEDERAL AND STATE LAW, THE MEMBERSHIP OF THE BOARD SHALL REFLECT THE**
 22 **RACIAL, ETHNIC, AND GENDER DIVERSITY OF THE STATE.**

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

24 **(2) THE TERMS OF THE MEMBERS AND ALTERNATE MEMBERS ARE**
 25 **STAGGERED AS REQUIRED BY THE TERMS PROVIDED FOR MEMBERS ON OCTOBER 1,**
 26 **2019.**

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

29 **(2) THE CHAIR SHALL DEVELOP A 5-YEAR BUDGET AND STAFFING**
 30 **PLAN AND SUBMIT IT TO THE BOARD FOR APPROVAL.**

1 ~~(2)~~ (3) STAFF OF THE BOARD SHALL RECEIVE A SALARY AS
2 PROVIDED IN THE BUDGET OF THE BOARD.

3 (D) A MEMBER OF THE BOARD:

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

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

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

11 (II) ~~THE~~ AT THE CHAIR'S DISCRETION, THE CHAIR MAY CANCEL
12 OR POSTPONE A MEETING ~~IF THERE ARE NO PRESCRIPTION DRUG PRODUCTS TO~~
13 ~~REVIEW.~~

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

16 1. THE STUDY REQUIRED UNDER § 21-2C-07;

17 ~~1.~~ 2. DELIBERATIONS ON WHETHER TO SUBJECT A
18 PRESCRIPTION DRUG PRODUCT TO A COST REVIEW UNDER ~~§ 21-2C-07(D)~~ §
19 21-2C-08(D) OF THIS SUBTITLE;

20 ~~2.~~ 3. ANY VOTE ON WHETHER TO IMPOSE AN UPPER
21 PAYMENT LIMIT ON PURCHASES AND PAYOR REIMBURSEMENTS OF PRESCRIPTION
22 DRUG PRODUCTS IN THE STATE; AND

23 ~~3.~~ 4. ANY DECISION BY THE BOARD.

24 (IV) NOTWITHSTANDING THE OPEN MEETINGS ACT, THE
25 BOARD MAY MEET IN CLOSED SESSION TO DISCUSS TRADE SECRETS OR
26 CONFIDENTIAL AND PROPRIETARY DATA AND INFORMATION.

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

29 (3) (1) MATERIALS FOR EACH BOARD MEETING SHALL BE MADE
30 AVAILABLE TO THE PUBLIC AT LEAST 1 WEEK IN ADVANCE OF THE MEETING.

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

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

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

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

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

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

16 **(II) ACCESSING OTHER AVAILABLE PRICING INFORMATION.**

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

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

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

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

30 **(II) FOR THE PURPOSES OF SUBPARAGRAPH (I) OF THIS**
31 **PARAGRAPH, A FINANCIAL BENEFIT INCLUDES HONORARIA, FEES, STOCK, THE**
32 **VALUE OF THE MEMBER'S OR IMMEDIATE FAMILY MEMBER'S STOCK HOLDINGS, AND**

1 ANY DIRECT FINANCIAL BENEFIT DERIVING FROM THE FINDING OF A REVIEW
2 CONDUCTED UNDER THIS SUBTITLE.

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

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

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

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

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

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

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

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

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

28 21-2C-04.

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

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

4 (C) (1) THE STAKEHOLDER COUNCIL CONSISTS OF ~~21~~ ~~25~~ 26 MEMBERS
 5 APPOINTED IN ACCORDANCE WITH THIS SUBSECTION.

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

7 (I) ONE REPRESENTATIVE OF GENERIC DRUG CORPORATIONS;

8 (II) ONE REPRESENTATIVE OF NONPROFIT INSURANCE
 9 CARRIERS;

10 ~~(III)~~ (III) ONE REPRESENTATIVE OF A STATEWIDE HEALTH
 11 CARE ADVOCACY COALITION;

12 ~~(IV)~~ (IV) ONE REPRESENTATIVE OF A STATEWIDE ADVOCACY
 13 ORGANIZATION FOR SENIORS;

14 ~~(V)~~ (V) ONE REPRESENTATIVE OF A STATEWIDE
 15 ORGANIZATION FOR DIVERSE COMMUNITIES;

16 ~~(VI)~~ (VI) ONE REPRESENTATIVE OF A LABOR UNION;

17 ~~(VII)~~ (VII) ~~TWO~~ ONE HEALTH SERVICES ~~RESEARCHERS~~
 18 RESEARCHER SPECIALIZING IN PRESCRIPTION DRUGS; AND

19 ~~(VIII)~~ (VIII) ONE PUBLIC MEMBER AT THE DISCRETION OF THE
 20 SPEAKER OF THE HOUSE OF DELEGATES.

21 (3) THE PRESIDENT OF THE SENATE SHALL APPOINT:

22 (I) ONE REPRESENTATIVE OF BRAND NAME DRUG
 23 CORPORATIONS;

24 ~~(II)~~ (II) ONE REPRESENTATIVE OF ~~DOCTORS~~ PHYSICIANS;

25 ~~(III)~~ (III) ONE REPRESENTATIVE OF NURSES;

26 ~~(IV)~~ (IV) ONE REPRESENTATIVE OF HOSPITALS;

27 (V) ONE REPRESENTATIVE OF DENTISTS;

1 ~~(IV)~~ ~~(V)~~ (VI) ONE REPRESENTATIVE OF ~~HEALTH INSURERS~~
 2 MANAGED CARE ORGANIZATIONS;

3 ~~(V)~~ ~~(VI)~~ (VII) ONE REPRESENTATIVE OF THE DEPARTMENT
 4 OF BUDGET AND MANAGEMENT;

5 ~~(VI)~~ ~~(VII)~~ (VIII) ONE CLINICAL RESEARCHER; AND

6 ~~(VII)~~ ~~(VIII)~~ (IX) ONE PUBLIC MEMBER AT THE DISCRETION OF
 7 THE PRESIDENT OF THE SENATE.

8 (4) THE GOVERNOR SHALL APPOINT:

9 (I) ONE REPRESENTATIVE OF BRAND NAME DRUG
 10 CORPORATIONS;

11 (II) ONE REPRESENTATIVE OF GENERIC DRUG CORPORATIONS;

12 (III) ONE REPRESENTATIVE OF BIOTECHNOLOGY COMPANIES;

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

15 ~~(III)~~ (V) ONE REPRESENTATIVE OF EMPLOYERS;

16 ~~(IV)~~ (VI) ONE REPRESENTATIVE OF PHARMACY BENEFITS
 17 MANAGERS;

18 ~~(V)~~ (VII) ONE REPRESENTATIVE OF PHARMACISTS;

19 ~~(VI)~~ (VIII) ONE PHARMACOLOGIST; AND

20 ~~(VII)~~ (IX) ONE PUBLIC MEMBER AT THE DISCRETION OF THE
 21 GOVERNOR.

22 (5) ~~THE~~ COLLECTIVELY, THE MEMBERS OF THE STAKEHOLDER
 23 COUNCIL SHALL HAVE KNOWLEDGE ~~IN ONE OR MORE~~ OF THE FOLLOWING:

24 (I) THE PHARMACEUTICAL BUSINESS MODEL;

25 (II) SUPPLY CHAIN BUSINESS MODELS;

26 (III) THE PRACTICE OF MEDICINE OR CLINICAL TRAINING;

1 (IV) CONSUMER OR PATIENT PERSPECTIVES;

2 (V) HEALTH CARE COSTS TRENDS AND DRIVERS;

3 (VI) CLINICAL AND HEALTH SERVICES RESEARCH; OR

4 (VII) THE STATE'S HEALTH CARE MARKETPLACE.

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

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

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

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

15 (E) A MEMBER OF THE STAKEHOLDER COUNCIL:

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

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

20 21-2C-05.

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

22 (I) BY THE BOARD WHEN HIRING BOARD STAFF;

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

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

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

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

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

5 **(B) (1) A CONFLICT OF INTEREST DISCLOSED UNDER SUBSECTION (A) OF**
6 **THIS SECTION SHALL BE POSTED ON THE WEBSITE OF THE BOARD UNLESS THE**
7 **CHAIR OF THE BOARD RECUSES THE MEMBER FROM ANY FINAL DECISION**
8 **RESULTING FROM A REVIEW OF A PRESCRIPTION DRUG PRODUCT.**

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

12 **21-2C-06.**

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

17 **21-2C-07.**

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

20 **(1) STUDY:**

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

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

25 **1. SETTING UPPER PAYMENT LIMITS;**

26 **2. USING A REVERSE AUCTION MARKETPLACE; AND**

27 **3. IMPLEMENTING A BULK PURCHASING PROCESS; AND**

28 **(2) REPORT ITS FINDINGS AND RECOMMENDATIONS, INCLUDING**
29 **FINDINGS FOR EACH OPTION STUDIED UNDER ITEM (1)(II) OF THIS SECTION AND**

1 ANY LEGISLATION REQUIRED TO IMPLEMENT THE RECOMMENDATIONS, TO THE
2 SENATE FINANCE COMMITTEE AND THE HOUSE HEALTH AND GOVERNMENT
3 OPERATIONS COMMITTEE IN ACCORDANCE WITH § 2-1246 OF THE STATE
4 GOVERNMENT ARTICLE.

5 21-2C-08.

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

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

10 (2) (i) ~~HOW DRUG SHORTAGES IMPACT THE COST OF~~
11 ~~PRESCRIPTION DRUG PRODUCTS;~~

12 (ii) ~~DIFFERENT CAUSES OF DRUG SHORTAGES; AND~~

13 (iii) ~~WHETHER UPPER PAYMENT LIMITS WOULD BE~~
14 ~~APPROPRIATE IN ADDRESSING COSTS IN THE EVENT OF A DRUG SHORTAGE OR~~
15 ~~WHETHER UPPER PAYMENT LIMITS WOULD EXACERBATE A DRUG SHORTAGE.~~

16 (B) ~~ON OR BEFORE DECEMBER 31, 2020, THE BOARD SHALL:~~

17 (1) ~~COLLECT AND REVIEW PUBLICLY AVAILABLE INFORMATION~~
18 ~~REGARDING PRESCRIPTION DRUG PRODUCT MANUFACTURERS, HEALTH INSURANCE~~
19 ~~CARRIERS, HEALTH MAINTENANCE ORGANIZATIONS, MANAGED CARE~~
20 ~~ORGANIZATIONS, WHOLESALE DISTRIBUTORS, AND PHARMACY BENEFITS~~
21 ~~MANAGERS; AND~~

22 (1) (2) (I) ~~IDENTIFY STATES THAT REQUIRE REPORTING ON THE~~
23 ~~COST OF PRESCRIPTION DRUG PRODUCTS; AND~~

24 (2) (II) ~~INITIATE A PROCESS OF ENTERING INTO MEMORANDA~~
25 ~~OF UNDERSTANDING WITH THE STATES IDENTIFIED UNDER ITEM (1) (I) OF THIS~~
26 ~~SUBSECTION ITEM TO AID IN THE COLLECTION OF TRANSPARENCY DATA FOR~~
27 ~~PRESCRIPTION DRUG PRODUCTS.~~

28 (C) (B) ~~BASED ON THE DETERMINATIONS MADE UNDER SUBSECTION (A)~~
29 ~~OF THIS SECTION AND THE DATA OBTAINED FROM STATES IDENTIFIED UNDER~~
30 ~~SUBSECTION (B) OF THIS SECTION, INFORMATION COLLECTED UNDER SUBSECTION~~
31 ~~(A)(1) OF THIS SECTION AND OBTAINED THROUGH MEMORANDA OF~~
32 ~~UNDERSTANDING UNDER SUBSECTION (A)(2) OF THIS SECTION, THE BOARD, IN~~

1 CONSULTATION WITH THE STAKEHOLDER COUNCIL, SHALL ADOPT REGULATIONS
2 TO:

3 (1) ESTABLISH METHODS FOR COLLECTING ADDITIONAL DATA
4 NECESSARY TO CARRY OUT ITS DUTIES UNDER THIS SECTION; SUBTITLE; AND

5 (2) IDENTIFY CIRCUMSTANCES UNDER WHICH THE COST OF A
6 PRESCRIPTION DRUG PRODUCT MAY CREATE OR HAS CREATED AFFORDABILITY
7 CHALLENGES FOR THE STATE HEALTH CARE SYSTEM AND PATIENTS; AND.

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

11 ~~21-2C-08.~~

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

16 ~~(B)~~ (C) THE BOARD SHALL USE THE INFORMATION COLLECTED UNDER
17 SUBSECTION (A)(1) OF THIS SECTION AND OBTAINED THROUGH MEMORANDA OF
18 UNDERSTANDING UNDER SUBSECTION (A)(2) OF THIS SECTION TO IDENTIFY
19 PRESCRIPTION DRUG PRODUCTS THAT ARE:

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

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

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

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

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

1 (I) OF \$100 OR MORE FOR:

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

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

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

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

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

19 21-2C-09.

20 ~~(C)~~ (A) (1) AFTER IDENTIFYING PRESCRIPTION DRUG PRODUCTS AS
21 REQUIRED BY ~~SUBSECTION (B) OF THIS SECTION~~ § 21-2C-08 OF THIS SUBTITLE, THE
22 BOARD SHALL DETERMINE WHETHER TO CONDUCT A COST REVIEW AS DESCRIBED
23 IN SUBSECTION ~~(D)~~ (B) OF THIS SECTION FOR EACH IDENTIFIED PRESCRIPTION
24 DRUG PRODUCT BY:

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

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

29 (2) (I) TO THE EXTENT THERE IS NO PUBLICLY AVAILABLE
30 INFORMATION TO CONDUCT A COST REVIEW AS DESCRIBED IN SUBSECTION ~~(D)~~ (B)
31 OF THIS SECTION, THE BOARD SHALL REQUEST THE INFORMATION FROM ~~THE~~:

1 **1. THE MANUFACTURER OF THE PRESCRIPTION DRUG**
 2 **PRODUCT; AND**

3 **2. AS APPROPRIATE, A WHOLESALE DISTRIBUTOR,**
 4 **PHARMACY BENEFITS MANAGER, HEALTH INSURANCE CARRIER, HEALTH**
 5 **MAINTENANCE ORGANIZATION, OR MANAGED CARE ORGANIZATION WITH RELEVANT**
 6 **INFORMATION ON SETTING THE COST OF A THE PRESCRIPTION DRUG PRODUCT IN**
 7 **THE STATE.**

8 **(II) THE INFORMATION TO CONDUCT A COST REVIEW MAY**
 9 **INCLUDE ANY DOCUMENT AND RESEARCH RELATED TO THE MANUFACTURER'S**
 10 **SELECTION OF THE INTRODUCTORY PRICE OR PRICE INCREASE OF THE**
 11 **PRESCRIPTION DRUG PRODUCT, INCLUDING LIFE CYCLE MANAGEMENT, NET**
 12 **AVERAGE PRICE IN THE STATE, MARKET COMPETITION AND CONTEXT, PROJECTED**
 13 **REVENUE, AND THE ESTIMATED VALUE OR COST-EFFECTIVENESS OF THE**
 14 **PRESCRIPTION DRUG PRODUCT.**

15 **(III) FAILURE OF A MANUFACTURER, WHOLESALE DISTRIBUTOR,**
 16 **PHARMACY BENEFITS MANAGER, HEALTH INSURANCE CARRIER, HEALTH**
 17 **MAINTENANCE ORGANIZATION, OR MANAGED CARE ORGANIZATION TO PROVIDE**
 18 **THE BOARD WITH THE INFORMATION REQUESTED UNDER THIS PARAGRAPH DOES**
 19 **NOT AFFECT THE AUTHORITY OF THE BOARD TO CONDUCT A REVIEW AS DESCRIBED**
 20 **IN SUBSECTION ~~(D)~~ (B) OF THIS SECTION ~~OR ESTABLISH AN UPPER PAYMENT LIMIT~~**
 21 **~~AS AUTHORIZED UNDER SUBSECTION (E) OF THIS SECTION.~~**

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

29 **(2) TO THE EXTENT PRACTICABLE, IN DETERMINING WHETHER A**
 30 **PRESCRIPTION DRUG PRODUCT IDENTIFIED UNDER ~~SUBSECTION (B) OF THIS~~**
 31 **~~SECTION~~ § 21-2C-08 OF THIS SUBTITLE HAS LED OR WILL LEAD TO AN**
 32 **AFFORDABILITY CHALLENGE, THE BOARD SHALL CONSIDER THE FOLLOWING**
 33 **FACTORS:**

34 **(I) THE WHOLESALE ACQUISITION COST AND ANY OTHER**
 35 **RELEVANT PRESCRIPTION DRUG COST INDEX FOR THE PRESCRIPTION DRUG**
 36 **PRODUCT SOLD IN THE STATE;**

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

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

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

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

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

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

25 **(VIII) THE CURRENT OR EXPECTED DOLLAR VALUE OF**
26 **DRUG-SPECIFIC PATIENT ACCESS PROGRAMS THAT ARE SUPPORTED BY THE**
27 **MANUFACTURER;**

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

31 **(X) THE AVERAGE PATIENT COPAY OR OTHER COST-SHARING**
32 **FOR THE PRESCRIPTION DRUG PRODUCT IN THE STATE; AND**

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

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

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

11 **(II) THE PORTION OF DIRECT-TO-CONSUMER MARKETING**
 12 **COSTS ELIGIBLE FOR FAVORABLE FEDERAL TAX TREATMENT IN THE MOST RECENT**
 13 **TAX YEAR THAT ARE SPECIFIC TO THE PRESCRIPTION DRUG PRODUCT UNDER**
 14 **REVIEW AND THAT ARE MULTIPLIED BY THE RATIO OF TOTAL MANUFACTURER**
 15 **IN-STATE SALES TO TOTAL MANUFACTURER SALES IN THE UNITED STATES FOR THE**
 16 **PRODUCT UNDER REVIEW;**

17 **(III) GROSS AND NET MANUFACTURER ~~AND~~ PHARMACY**
 18 **BENEFITS MANAGER, AND WHOLESALE DISTRIBUTOR REVENUES FOR THE**
 19 **PRESCRIPTION DRUG PRODUCT UNDER REVIEW FOR THE MOST RECENT TAX YEAR;**

20 **(IV) ANY ADDITIONAL FACTORS PROPOSED BY THE**
 21 **MANUFACTURER AND APPROPRIATE HEALTH INSURANCE CARRIERS, HEALTH**
 22 **MAINTENANCE ORGANIZATIONS, MANAGED CARE ORGANIZATIONS, WHOLESALE**
 23 **DISTRIBUTORS, AND PHARMACY BENEFITS MANAGERS THAT THE BOARD CONSIDERS**
 24 **RELEVANT; AND**

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

27 ~~**(E) (1) IF THE BOARD FINDS THAT THE SPENDING ON A PRESCRIPTION**~~
 28 ~~**DRUG PRODUCT REVIEWED UNDER THIS SECTION HAS LED OR WILL LEAD TO AN**~~
 29 ~~**AFFORDABILITY CHALLENGE, THE BOARD SHALL RECOMMEND OR ESTABLISH SET**~~
 30 ~~**AN UPPER PAYMENT LIMIT UNDER PARAGRAPH (2) OR (3) OF THIS SUBSECTION §**~~
 31 ~~**21-2C-09 OF THIS SUBTITLE AFTER CONSIDERING:**~~

32 ~~**(I) (1) THE COST OF ADMINISTERING THE DRUG;**~~

33 ~~**(II) (2) THE COST OF DELIVERING THE DRUG TO**~~
 34 ~~**CONSUMERS; AND**~~

1 ~~(H) (3) OTHER RELEVANT ADMINISTRATIVE COSTS RELATED~~
2 ~~TO THE DRUG; AND~~

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

12 ~~21-2C-09.~~

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

15 (C) ON OR BEFORE DECEMBER 31, 2020, AND EACH DECEMBER 31
16 THEREAFTER, THE BOARD SHALL SUBMIT TO THE SENATE FINANCE COMMITTEE
17 AND THE HOUSE HEALTH AND GOVERNMENT OPERATIONS COMMITTEE, IN
18 ACCORDANCE WITH § 2-1246 OF THE STATE GOVERNMENT ARTICLE, A REPORT
19 THAT INCLUDES:

20 (1) PRICE TRENDS FOR PRESCRIPTION DRUG PRODUCTS;

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

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

26 ~~21-2C-10.~~

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

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

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

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

6 (C) THE PROVISIONS OF TITLE 11, SUBTITLE 12 OF THE COMMERCIAL LAW
7 ARTICLE SHALL APPLY TO ANY TRADE SECRETS AND CONFIDENTIAL AND
8 PROPRIETARY DATA AND INFORMATION OBTAINED UNDER THIS SUBTITLE THAT IS
9 NOT OTHERWISE PUBLICLY AVAILABLE.

10 21-2C-11.

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

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

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

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

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

21 (C) ON OR BEFORE DECEMBER 31, 2020, IN ACCORDANCE WITH § 2-1246 OF
22 THE STATE GOVERNMENT ARTICLE, THE BOARD SHALL REPORT BACK TO THE
23 SENATE FINANCE COMMITTEE AND THE HOUSE HEALTH AND GOVERNMENT
24 OPERATIONS COMMITTEE WITH A RECOMMENDATION ON LEGISLATION NECESSARY
25 TO ESTABLISH A FUNDING SOURCE FOR THE BOARD.

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

29 21-2C-12.

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

1 ACTION TO THE LEGISLATIVE POLICY COMMITTEE OF THE GENERAL ASSEMBLY, IN
 2 ACCORDANCE WITH § 2-1246 OF THE STATE GOVERNMENT ARTICLE, FOR ITS
 3 APPROVAL.

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

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

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

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

13 (I) THE LEGISLATIVE POLICY COMMITTEE; OR

14 (II) 1. THE GOVERNOR; AND

15 2. THE ATTORNEY GENERAL.

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

18 Article – Health – General

19 21-2C-13.

20 ~~(B)~~ (A) ON OR AFTER ~~JULY 1, 2021~~ JANUARY 1, 2022, THE BOARD SHALL
 21 MAY SET UPPER PAYMENT LIMITS FOR PRESCRIPTION DRUG PRODUCTS THAT ARE:

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

25 (I) STATE OR COUNTY CORRECTIONAL FACILITIES;

26 (II) STATE HOSPITALS; AND

27 (III) HEALTH CLINICS AT STATE INSTITUTIONS OF HIGHER
 28 EDUCATION; ~~OR~~

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

4 (3) PURCHASED FOR OR PAID FOR BY THE MARYLAND STATE
 5 MEDICAL ASSISTANCE PROGRAM.

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

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

10 (2) BE SET IN ACCORDANCE WITH THE CRITERIA ESTABLISHED ~~IN~~
 11 ~~REGULATIONS UNDER § 21-2C-07(C)(3) OF THIS SUBTITLE~~ IN REGULATIONS
 12 ADOPTED BY THE BOARD.

13 ~~(D)~~ (C) (1) THE BOARD SHALL:

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

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

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

23 ~~21-2C-10.~~

24 ~~ALL INFORMATION AND DATA COLLECTED BY THE BOARD DURING A REVIEW~~
 25 ~~UNDER THIS SUBTITLE;~~

26 ~~(1) IS CONSIDERED TO BE CONFIDENTIAL AND PROPRIETARY~~
 27 ~~INFORMATION; AND~~

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

30 ~~21-2C-08. 21-2C-11.~~

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

~~21-2C-09. 21-2C-12. 21-2C-14.~~

(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. 21-2C-13.~~

~~(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.~~

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

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

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

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

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

13 ~~(A) (1) ON OR BEFORE DECEMBER 31, 2020, THE BOARD SHALL~~
14 ~~DETERMINE A FUNDING SOURCE FOR THE BOARD.~~

15 ~~(2) IN DETERMINING A FUNDING SOURCE, THE BOARD SHALL~~
16 ~~CONSIDER:~~

17 ~~(I) ASSESSING AND COLLECTING A FEE ON MANUFACTURERS,~~
18 ~~PHARMACY BENEFIT MANAGERS, HEALTH INSURANCE CARRIERS, OR OTHER~~
19 ~~ENTITIES;~~

20 ~~(II) USING REBATES THE STATE OR LOCAL GOVERNMENT~~
21 ~~RECEIVES FROM MANUFACTURERS; AND~~

22 ~~(III) ANY OTHER METHOD IT DETERMINES APPROPRIATE FOR~~
23 ~~FUNDING THE BOARD.~~

24 ~~(3) ON OR BEFORE DECEMBER 31, 2020, THE BOARD SHALL REPORT~~
25 ~~BACK TO THE SENATE FINANCE COMMITTEE AND THE HOUSE HEALTH AND~~
26 ~~GOVERNMENT OPERATIONS COMMITTEE WITH A RECOMMENDATION ON~~
27 ~~LEGISLATION NECESSARY TO ESTABLISH A FUNDING SOURCE FOR THE BOARD.~~

28 ~~(D) (B) THE BOARD SHALL BE ESTABLISHED USING GENERAL FUNDS,~~
29 ~~WHICH SHALL BE REPAID TO THE STATE WITH THE ASSESSMENTS REQUIRED UNDER~~
30 ~~THIS SECTION FUNDS FROM THE FUNDING SOURCE DETERMINED BY THE BOARD~~
31 ~~UNDER SUBSECTION (A) OF THIS SECTION.~~

32 ~~21-2C-11. 21-2C-14.~~

~~ON OR BEFORE DECEMBER 31, 2021, AND EACH YEAR DECEMBER 31 THEREAFTER, THE BOARD SHALL SUBMIT TO THE SENATE FINANCE COMMITTEE AND THE HOUSE HEALTH AND GOVERNMENT OPERATIONS COMMITTEE, IN ACCORDANCE WITH § 2-1246 OF THE STATE GOVERNMENT ARTICLE, A REPORT THAT INCLUDES:~~

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

~~(2) THE NUMBER OF PRESCRIPTION DRUG PRODUCTS THAT WERE SUBJECT TO BOARD REVIEW, 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.~~

~~21-2C-15.~~

~~ON OR BEFORE DECEMBER 1, 2023, THE BOARD, IN CONSULTATION WITH THE STAKEHOLDER COUNCIL, SHALL REPORT TO THE SENATE FINANCE COMMITTEE AND THE HOUSE HEALTH AND GOVERNMENT OPERATIONS COMMITTEE, IN ACCORDANCE WITH § 2-1246 OF THE STATE GOVERNMENT ARTICLE, ON:~~

~~(1) THE LEGALITY, OBSTACLES, AND BENEFITS OF SETTING UPPER PAYMENT LIMITS ON ALL PURCHASES AND PAYOR REIMBURSEMENTS OF PRESCRIPTION DRUG PRODUCTS IN THE STATE; AND~~

~~(2) RECOMMENDATIONS REGARDING WHETHER THE GENERAL ASSEMBLY SHOULD PASS LEGISLATION TO EXPAND THE AUTHORITY OF THE BOARD TO SET UPPER PAYMENT LIMITS TO ALL PURCHASES AND PAYOR REIMBURSEMENTS OF PRESCRIPTION DRUG PRODUCTS IN THE STATE.~~

~~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.~~

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

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

4 ~~113. the Veteran Employment and Transition Success Fund;~~

5 ~~AND~~

6 ~~114. THE PRESCRIPTION DRUG AFFORDABILITY FUND.~~

7 SECTION ~~2~~ 4. AND BE IT FURTHER ENACTED, That:

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

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

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

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

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

16 (1) ~~seven~~ eight members in 2022;

17 (2) ~~seven~~ eight *nine* members in 2023; and

18 (3) ~~seven~~ nine members in 2024.

19 SECTION ~~2~~ 5. AND BE IT FURTHER ENACTED, That, on or before June 1, 2020,
 20 the Prescription Drug Affordability Board shall:

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

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

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

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

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

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

3 (vi) any other relevant study questions; and

4 (2) report its findings to the General Assembly, in accordance with §
5 2–1246 of the State Government Article.

6 SECTION ~~4~~ 6. AND BE IT FURTHER ENACTED, That, on or before January 1,
7 2023, the ~~Health Services Cost Review Commission~~ Prescription Drug Affordability Board
8 established under § 21–2C–02 of the Health – General Article, as enacted by Section 1 of
9 this Act, in consultation with the Prescription Drug Affordability Stakeholder Council
10 established under § 21–2C–04 of the Health – General Article, as enacted by Section 1 of
11 this Act, the Health Services Cost Review Commission, and the Maryland Health Care
12 Commission, shall:

13 (1) monitor and assess the impact of ~~upper payment limits and~~ policy
14 actions, including, if applicable, upper payment limits, by the Prescription Drug
15 Affordability Board on:

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

18 (ii) the ability of hospitals and other providers to obtain drugs from
19 manufacturers and suppliers at costs consistent with ~~the upper payment limits established~~
20 policy actions, including, if applicable, upper payment limits, by the Board; and

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

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

25 ~~SECTION 5. AND BE IT FURTHER ENACTED, That, on or before December 1,~~
26 ~~2023, the Prescription Drug Affordability Board established under § 21–2C–02 of the~~
27 ~~Health – General Article, as enacted by Section 1 of this Act, in consultation with the~~
28 ~~Prescription Drug Affordability Stakeholder Council established under § 21–2C–04 of the~~
29 ~~Health – General Article, as enacted by Section 1 of this Act, shall report to the Senate~~
30 ~~Finance Committee and the House Health and Government Operations Committee, in~~
31 ~~accordance with § 2–1246 of the State Government Article, on:~~

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

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

1 SECTION ~~6~~ 7. AND BE IT FURTHER ENACTED, That, on or before December 1,
2 2020, the State Designated Health Information Exchange and the Prescription Drug
3 Affordability Board established under § 21-2C-02 of the Health – General Article, as
4 enacted by Section 1 of this Act, jointly shall:

5 (1) study how the Information Exchange can provide de-identified
6 provider and patient data to the Board; and

7 (2) report their findings and recommendations, including any necessary
8 statutory changes, to the General Assembly, in accordance with § 2-1246 of the State
9 Government Article.

10 SECTION ~~5~~ ~~7~~ 8. AND BE IT FURTHER ENACTED, That, if any provision of this
11 Act or the application thereof to any person or circumstance is held invalid for any reason
12 in a court of competent jurisdiction, the invalidity does not affect other provisions or any
13 other application of this Act that can be given effect without the invalid provision or
14 application, and for this purpose the provisions of this Act are declared severable.

15 SECTION 9. AND BE IT FURTHER ENACTED, That Section 3 of this Act shall take
16 effect contingent on receipt by the Prescription Drug Affordability Board established under
17 § 21-2C-02 of the Health – General Article, as enacted by Section 1 of this Act of approval
18 by the Legislative Policy Committee of the General Assembly or the Governor and the
19 Attorney General of the plan of action for implementing a process for setting upper payment
20 limits in accordance with § 21-2C-13 of the Health – General Article, as enacted by Section
21 2 of this Act. The Board, within 5 days after receiving approval from the Legislative Policy
22 Committee or the Governor and the Attorney General, shall forward evidence of the approval
23 to the Department of Legislative Services, 90 State Circle, Annapolis, Maryland 21401. If
24 the Board receives approval for the plan of action on or before January 1, 2023, Section 2 of
25 this Act, with no further action required by the General Assembly, shall be abrogated and of
26 no further force and effect and Section 3 of this Act shall take effect on the date evidence of
27 the approval is received by the Department of Legislative Services in accordance with this
28 section. If the Board does not receive approval of the plan of action on or before January 1,
29 2023, Section 2 of this Act, with no further action required by the General Assembly, shall
30 be abrogated and of no further force and effect and Section 3 of this Act shall be null and
31 void.

32 SECTION ~~6~~ ~~8~~ 10. AND BE IT FURTHER ENACTED, That, subject to Section 9 of
33 this Act, this Act shall take effect ~~October~~ July 1, 2019.