

HOUSE BILL 768

J1, C3

9lr0936
CF SB 759

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**

Introduced and read first time: February 8, 2019
Assigned to: Health and Government Operations

Committee Report: Favorable with amendments
House action: Adopted
Read second time: March 18, 2019

CHAPTER _____

1 AN ACT concerning

2 **Health – Prescription Drug Affordability Board**

3 FOR the purpose of establishing the Prescription Drug Affordability Board as an
4 independent unit of State government; providing that the exercise by the Board of
5 its authority under this Act is an essential governmental function; providing for the
6 purpose of the Board; providing for the membership, terms, compensation, and chair
7 of the Board; requiring certain conflicts of interest to be disclosed and considered
8 when appointing members to the Board; specifying the terms of the initial members
9 and alternate members of the Board; requiring the chair of the Board to hire certain
10 staff and develop a certain budget and plan to be submitted to the Board for approval;
11 requiring that the staff of the Board receive a certain salary; requiring the Board to
12 meet in a certain manner and with a certain frequency with certain exceptions;

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.



1 requiring the Board to provide certain public notice of each Board meeting and to
2 make certain materials available to the public in a certain manner; requiring the
3 Board to provide the public with the opportunity to provide certain comments;
4 authorizing the Board to allow expert testimony under certain circumstances;
5 requiring the Board to access certain information for prescription drug products in a
6 certain manner; requiring certain actions by the Board to be made in open session;
7 providing that a majority of the members of the Board constitutes a quorum;
8 requiring members of the Board to recuse themselves from certain decisions under
9 certain circumstances; authorizing the Board to adopt certain regulations and enter
10 into certain contracts; providing that certain third parties may not use certain
11 information except under certain circumstances; providing for the application of
12 certain procurement law to the Board; establishing the Prescription Drug
13 Affordability Stakeholder Council; providing for the purpose of the Stakeholder
14 Council; providing for the membership of the Stakeholder Council; specifying the
15 terms of the initial members of the Stakeholder Council; requiring the Board to
16 appoint certain chairs for the Stakeholder Council; prohibiting a member of the
17 Stakeholder Council from receiving certain compensation, but authorizing the
18 reimbursement of certain expenses; requiring the disclosure of certain conflicts of
19 interest within a certain time frame and in a certain manner; prohibiting certain
20 persons from accepting certain gifts or donations; providing for the construction of
21 certain provisions of this Act; requiring the Board in consultation with the
22 Stakeholder Council to make certain determinations and adopt certain regulations
23 on or before a certain date; requiring the Board to identify certain states and initiate
24 a certain process on or before a certain date; requiring the Board to identify certain
25 prescription drug products with certain costs; requiring the Board to determine in a
26 certain manner whether to conduct a certain review for certain identified products;
27 requiring the Board to request certain information from ~~a manufacturer~~ certain
28 entities under certain circumstances; providing that information to conduct a certain
29 cost review includes certain documents and research; providing that failure of ~~a~~
30 ~~manufacturer~~ certain entities to provide the Board with certain information does not
31 affect certain Board authority; requiring that a certain review determine if certain
32 utilization of a prescription drug product has led or will lead to certain challenges;
33 requiring the Board to consider certain factors in making a certain determination on
34 whether a certain drug product has led or will lead to certain challenges; authorizing
35 the Board to consider certain additional factors if the Board is unable to make a
36 certain determination; requiring the Board to ~~recommend or establish~~ set certain
37 upper payment limits after considering certain factors; ~~requiring the Board to work~~
38 ~~with certain stakeholders to identify certain methodologies and establish certain~~
39 ~~data sources on or before a certain date; providing for the application of certain~~
40 ~~provisions of this Act; requiring the Board to consider certain information and~~
41 ~~recommend and publicize certain upper payment limits on or before a certain date;~~
42 requiring the Board to ~~establish~~ set certain upper payment limits for certain
43 prescription drug products on or after a certain date; ~~requiring that certain~~
44 ~~information be subject to public inspection to the extent allowed under certain~~
45 ~~provisions of law; requiring the Board to monitor the availability of certain~~
46 prescription drug products and reconsider upper payment limits under certain
47 circumstances; prohibiting upper payment limits from applying to a prescription

1 drug product while the prescription drug product is on a certain federal list;
 2 providing that certain information and data is considered confidential and
 3 proprietary and is not subject to disclosure under certain provisions of law;
 4 authorizing the Office of the Attorney General to pursue certain remedies;
 5 authorizing certain appeals and judicial review of certain Board decisions;
 6 ~~establishing the Prescription Drug Affordability Fund; requiring the Board to be~~
 7 ~~funded by a certain assessment; requiring the Board to assess and collect certain~~
 8 ~~fees; requiring the State Treasurer to hold the Fund separately, and the Comptroller~~
 9 ~~to account for the Fund; providing that the Fund is not subject to certain provisions~~
 10 ~~of law but is subject to certain audit by the Office of Legislative Audits; requiring the~~
 11 Board to determine a certain funding source and submit a certain recommendation
 12 to certain committees of the General Assembly on or before a certain date; requiring
 13 the Board to be funded in a certain manner; requiring the Board to submit certain
 14 reports to certain committees of the General Assembly and to the General Assembly
 15 on or before certain dates; requiring the Health Services Cost Review Commission,
 16 ~~in consultation with the Maryland Health Care Commission, to submit a certain~~
 17 ~~report to the General Assembly on or before a certain date; requiring the State~~
 18 Designated Health Information Exchange Board jointly to conduct a study with the
 19 Board on providing certain data and report certain findings and recommendations
 20 to the General Assembly on or before a certain date; defining certain terms; making
 21 the provisions of this Act severable; and generally relating to the Prescription Drug
 22 Affordability Board.

23 BY adding to

24 Article – Health – General

25 Section 21-2C-01 through ~~21-2C-11~~ 21-2C-14 to be under the new subtitle

26 “Subtitle 2C. Prescription Drug Affordability Board”

27 Annotated Code of Maryland

28 (2015 Replacement Volume and 2018 Supplement)

29 ~~BY repealing and reenacting, without amendments,~~

30 ~~Article – State Finance and Procurement~~

31 ~~Section 6-226(a)(2)(i)~~

32 ~~Annotated Code of Maryland~~

33 ~~(2015 Replacement Volume and 2018 Supplement)~~

34 ~~BY repealing and reenacting, with amendments,~~

35 ~~Article – State Finance and Procurement~~

36 ~~Section 6-226(a)(2)(ii)112. and 113.~~

37 ~~Annotated Code of Maryland~~

38 ~~(2015 Replacement Volume and 2018 Supplement)~~

39 ~~BY adding to~~

40 ~~Article – State Finance and Procurement~~

41 ~~Section 6-226(a)(2)(ii)114.~~

42 ~~Annotated Code of Maryland~~

43 ~~(2015 Replacement Volume and 2018 Supplement)~~

Preamble

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

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

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

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

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

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

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

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

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

Article – Health – General**SUBTITLE 2C. PRESCRIPTION DRUG AFFORDABILITY BOARD.****21-2C-01.**

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

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

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

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

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

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

15 (F) "GENERIC DRUG" MEANS:

16 (1) A RETAIL DRUG THAT IS MARKETED OR DISTRIBUTED IN
17 ACCORDANCE WITH AN ABBREVIATED NEW DRUG APPLICATION, APPROVED UNDER
18 21 U.S.C. § 355(j);

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

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

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

23 (1) (i) ENGAGES IN THE MANUFACTURE OF A PRESCRIPTION DRUG
24 PRODUCT; OR

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

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

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

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

5 **21-2C-02.**

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

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

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

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

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

18 **21-2C-03.**

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

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

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

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

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

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

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

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

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

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

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

12 **(I) THE 340B PROGRAM UNDER THE FEDERAL PUBLIC**
13 **HEALTH SERVICE ACT;**

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

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

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

18 ~~**(3)**~~ **(4) A MEMBER OR AN ALTERNATE MEMBER MAY NOT BE AN**
19 **EMPLOYEE OF, A BOARD MEMBER OF, OR A CONSULTANT TO A MANUFACTURER OR**
20 **TRADE ASSOCIATION FOR MANUFACTURERS.**

21 ~~**(4)**~~ **(5) ANY CONFLICT OF INTEREST, INCLUDING WHETHER THE**
22 **INDIVIDUAL HAS AN ASSOCIATION, INCLUDING A FINANCIAL OR PERSONAL**
23 **ASSOCIATION, THAT HAS THE POTENTIAL TO BIAS OR HAS THE APPEARANCE OF**
24 **BIASING AN INDIVIDUAL'S DECISION IN MATTERS RELATED TO THE BOARD OR THE**
25 **CONDUCT OF THE BOARD'S ACTIVITIES, SHALL BE CONSIDERED AND DISCLOSED**
26 **WHEN APPOINTING MEMBERS AND ALTERNATE MEMBERS TO THE BOARD.**

27 ~~**(5)**~~ **(6) TO THE EXTENT PRACTICABLE AND CONSISTENT WITH**
28 **FEDERAL AND STATE LAW, THE MEMBERSHIP OF THE BOARD SHALL REFLECT THE**
29 **RACIAL, ETHNIC, AND GENDER DIVERSITY OF THE STATE.**

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

1 **(2) THE TERMS OF THE MEMBERS AND ALTERNATE MEMBERS ARE**
2 **STAGGERED AS REQUIRED BY THE TERMS PROVIDED FOR MEMBERS ON OCTOBER 1,**
3 **2019.**

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

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

8 ~~**(2)**~~ **(3) STAFF OF THE BOARD SHALL RECEIVE A SALARY AS**
9 **PROVIDED IN THE BUDGET OF THE BOARD.**

10 **(D) A MEMBER OF THE BOARD:**

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

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

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

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

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

22 1. **DELIBERATIONS ON WHETHER TO SUBJECT A**
23 **PRESCRIPTION DRUG PRODUCT TO A COST REVIEW UNDER ~~§ 21-2C-07(D)~~ §**
24 **21-2C-08(D) OF THIS SUBTITLE;**

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

28 3. **ANY DECISION BY THE BOARD.**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

31 **21-2C-04.**

32 **(A) THERE IS A PRESCRIPTION DRUG AFFORDABILITY STAKEHOLDER**
33 **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 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 ~~(I)~~ (III) ONE REPRESENTATIVE OF A STATEWIDE HEALTH
 11 CARE ADVOCACY COALITION;

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

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

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

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

19 ~~(VI)~~ (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 ~~(I)~~ (II) ONE REPRESENTATIVE OF ~~DOCTORS~~ PHYSICIANS;

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

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

27 ~~(IV)~~ (V) ONE REPRESENTATIVE OF ~~HEALTH INSURERS~~
 28 MANAGED CARE ORGANIZATIONS;

1 ~~(V)~~ (VI) ONE REPRESENTATIVE OF THE DEPARTMENT OF
2 BUDGET AND MANAGEMENT;

3 ~~(VI)~~ (VII) ONE CLINICAL RESEARCHER; AND

4 ~~(VII)~~ (VIII) ONE PUBLIC MEMBER AT THE DISCRETION OF THE
5 PRESIDENT OF THE SENATE.

6 (4) THE GOVERNOR SHALL APPOINT:

7 (I) ONE REPRESENTATIVE OF BRAND NAME DRUG
8 CORPORATIONS;

9 (II) ONE REPRESENTATIVE OF GENERIC DRUG CORPORATIONS;

10 (III) ONE REPRESENTATIVE OF BIOTECHNOLOGY COMPANIES;

11 (IV) ONE REPRESENTATIVE OF FOR PROFIT HEALTH INSURANCE
12 CARRIERS;

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

14 ~~(IV)~~ (VI) ONE REPRESENTATIVE OF PHARMACY BENEFITS
15 MANAGERS;

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

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

18 ~~(VII)~~ (IX) ONE PUBLIC MEMBER AT THE DISCRETION OF THE
19 GOVERNOR.

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

22 (I) THE PHARMACEUTICAL BUSINESS MODEL;

23 (II) SUPPLY CHAIN BUSINESS MODELS;

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

25 (IV) CONSUMER OR PATIENT PERSPECTIVES;

26 (V) HEALTH CARE COSTS TRENDS AND DRIVERS;

1 (VI) CLINICAL AND HEALTH SERVICES RESEARCH; OR

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

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

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

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

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

13 (E) A MEMBER OF THE STAKEHOLDER COUNCIL:

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

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

18 21-2C-05.

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

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

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

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

27 (2) A CONFLICT OF INTEREST SHALL BE DISCLOSED:

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

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

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

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

9 21-2C-06.

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

14 21-2C-07.

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

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

19 (2) (I) HOW DRUG SHORTAGES IMPACT THE COST OF
20 PRESCRIPTION DRUG PRODUCTS;

21 (II) DIFFERENT CAUSES OF DRUG SHORTAGES; AND

22 (III) WHETHER UPPER PAYMENT LIMITS WOULD BE
23 APPROPRIATE IN ADDRESSING COSTS IN THE EVENT OF A DRUG SHORTAGE OR
24 WHETHER UPPER PAYMENT LIMITS WOULD EXACERBATE A DRUG SHORTAGE.

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

26 (1) IDENTIFY STATES THAT REQUIRE REPORTING ON THE COST OF
27 PRESCRIPTION DRUG PRODUCTS; AND

28 (2) INITIATE A PROCESS OF ENTERING INTO MEMORANDA OF
29 UNDERSTANDING WITH THE STATES IDENTIFIED UNDER ITEM (1) OF THIS

1 SUBSECTION TO AID IN THE COLLECTION OF TRANSPARENCY DATA FOR
2 PRESCRIPTION DRUG PRODUCTS.

3 (C) BASED ON THE DETERMINATIONS MADE UNDER SUBSECTION (A) OF
4 THIS SECTION AND THE DATA OBTAINED FROM STATES IDENTIFIED UNDER
5 SUBSECTION (B) OF THIS SECTION, THE BOARD, IN CONSULTATION WITH THE
6 STAKEHOLDER COUNCIL, SHALL ADOPT REGULATIONS TO:

7 (1) ESTABLISH METHODS FOR COLLECTING DATA NECESSARY TO
8 CARRY OUT ITS DUTIES UNDER THIS SECTION;

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

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

15 21-2C-08.

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

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

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

25 (i) A LAUNCH WHOLESALE ACQUISITION COST OF \$30,000 OR
26 MORE PER YEAR OR COURSE OF TREATMENT; OR

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

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

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

4 **(I) OF \$100 OR MORE FOR:**

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

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

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

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

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

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

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

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

30 **(2) (I) TO THE EXTENT THERE IS NO PUBLICLY AVAILABLE**
31 **INFORMATION TO CONDUCT A COST REVIEW AS DESCRIBED IN SUBSECTION (D) OF**
32 **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 PHARMACY BENEFITS MANAGER,**
4 **HEALTH INSURANCE CARRIER, HEALTH MAINTENANCE ORGANIZATION, OR**
5 **MANAGED CARE ORGANIZATION WITH RELEVANT INFORMATION ON SETTING THE**
6 **COST OF A PRESCRIPTION DRUG PRODUCT IN THE STATE.**

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

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

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

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

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

35 **(II) THE AVERAGE MONETARY PRICE CONCESSION, DISCOUNT,**
36 **OR REBATE THE MANUFACTURER PROVIDES TO HEALTH PLANS IN THE STATE OR IS**
37 **EXPECTED TO PROVIDE TO HEALTH PLANS IN THE STATE AS REPORTED BY**

1 MANUFACTURERS AND HEALTH PLANS, EXPRESSED AS A PERCENT OF THE
2 WHOLESALE ACQUISITION COST FOR THE PRESCRIPTION DRUG PRODUCT UNDER
3 REVIEW;

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

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

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

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

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

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

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

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

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

32 (3) IF THE BOARD IS UNABLE TO DETERMINE WHETHER A
33 PRESCRIPTION DRUG PRODUCT WILL PRODUCE OR HAS PRODUCED CHALLENGES TO
34 THE AFFORDABILITY OF THE DRUG FOR THE STATE HEALTH CARE SYSTEM, USING

1 THE FACTORS LISTED IN PARAGRAPH (2) OF THIS SUBSECTION, THE BOARD MAY
2 CONSIDER THE FOLLOWING FACTORS:

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

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

14 (III) GROSS AND NET MANUFACTURER AND PHARMACY
15 BENEFITS MANAGER REVENUES FOR THE PRESCRIPTION DRUG PRODUCT UNDER
16 REVIEW FOR THE MOST RECENT TAX YEAR;

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

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

21 (E) ~~(1)~~ IF THE BOARD FINDS THAT THE SPENDING ON A PRESCRIPTION
22 DRUG PRODUCT REVIEWED UNDER THIS SECTION HAS LED OR WILL LEAD TO AN
23 AFFORDABILITY CHALLENGE, THE BOARD SHALL ~~RECOMMEND OR ESTABLISH SET~~
24 AN UPPER PAYMENT LIMIT UNDER ~~PARAGRAPH (2) OR (3) OF THIS SUBSECTION~~ §
25 21-2C-09 OF THIS SUBTITLE AFTER CONSIDERING:

26 ~~(1)~~ (1) THE COST OF ADMINISTERING THE DRUG;

27 ~~(2)~~ (2) THE COST OF DELIVERING THE DRUG TO
28 CONSUMERS; AND

29 ~~(3)~~ (3) OTHER RELEVANT ADMINISTRATIVE COSTS RELATED
30 TO THE DRUG; AND

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

21-2C-09.

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

(B) ON OR AFTER JULY 1, 2021, THE BOARD SHALL SET UPPER PAYMENT LIMITS FOR PRESCRIPTION DRUG PRODUCTS THAT ARE:

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

(I) STATE OR COUNTY CORRECTIONAL FACILITIES;

(II) STATE HOSPITALS; AND

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

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

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

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

(2) BE SET IN ACCORDANCE WITH THE CRITERIA ESTABLISHED IN REGULATIONS UNDER § 21-2C-07(C)(3) OF THIS SUBTITLE.

(D) (1) THE BOARD SHALL:

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

3 **(II) IF THERE BECOMES A SHORTAGE OF THE PRESCRIPTION**
4 **DRUG PRODUCT IN THE STATE, RECONSIDER WHETHER THE UPPER PAYMENT LIMIT**
5 **SHOULD BE SUSPENDED OR ALTERED.**

6 **(2) AN UPPER PAYMENT LIMIT SET UNDER SUBSECTION (B) OF THIS**
7 **SECTION MAY NOT BE APPLIED TO A PRESCRIPTION DRUG PRODUCT WHILE THE**
8 **PRESCRIPTION DRUG PRODUCT IS ON THE FEDERAL FOOD AND DRUG**
9 **ADMINISTRATION PRESCRIPTION DRUG SHORTAGE LIST.**

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

11 **ALL INFORMATION AND DATA COLLECTED BY THE BOARD DURING A REVIEW**
12 **UNDER THIS SUBTITLE:**

13 **(1) IS CONSIDERED TO BE CONFIDENTIAL AND PROPRIETARY**
14 **INFORMATION; AND**

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

17 ~~**21-2C-08.**~~ **21-2C-11.**

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

20 ~~**21-2C-09.**~~ **21-2C-12.**

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

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

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

28 ~~**21-2C-10.**~~ **21-2C-13.**

29 ~~**(A) IN THIS SECTION, “FUND” MEANS THE PRESCRIPTION DRUG**~~
30 ~~**AFFORDABILITY FUND.**~~

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

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

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

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

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

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

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

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

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

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

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

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

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

29 (A) (1) ON OR BEFORE DECEMBER 31, 2020, THE BOARD SHALL
30 DETERMINE A FUNDING SOURCE FOR THE BOARD.

1 **(2) IN DETERMINING A FUNDING SOURCE, THE BOARD SHALL**
 2 **CONSIDER:**

3 **(I) ASSESSING AND COLLECTING A FEE ON MANUFACTURERS,**
 4 **PHARMACY BENEFIT MANAGERS, HEALTH INSURANCE CARRIERS, OR OTHER**
 5 **ENTITIES;**

6 **(II) USING REBATES THE STATE OR LOCAL GOVERNMENT**
 7 **RECEIVES FROM MANUFACTURERS; AND**

8 **(III) ANY OTHER METHOD IT DETERMINES APPROPRIATE FOR**
 9 **FUNDING THE BOARD.**

10 **(3) ON OR BEFORE DECEMBER 31, 2020, THE BOARD SHALL REPORT**
 11 **BACK TO THE SENATE FINANCE COMMITTEE AND THE HOUSE HEALTH AND**
 12 **GOVERNMENT OPERATIONS COMMITTEE WITH A RECOMMENDATION ON**
 13 **LEGISLATION NECESSARY TO ESTABLISH A FUNDING SOURCE FOR THE BOARD.**

14 **(D) (B) THE BOARD SHALL BE ESTABLISHED USING GENERAL FUNDS,**
 15 **WHICH SHALL BE REPAID TO THE STATE WITH THE ASSESSMENTS REQUIRED UNDER**
 16 **THIS SECTION FUNDS FROM THE FUNDING SOURCE DETERMINED BY THE BOARD**
 17 **UNDER SUBSECTION (A) OF THIS SECTION.**

18 ~~21-2C-11.~~ 21-2C-14.

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

24 **(1) PRICE TRENDS FOR PRESCRIPTION DRUG PRODUCTS;**

25 **(2) THE NUMBER OF PRESCRIPTION DRUG PRODUCTS THAT WERE**
 26 **SUBJECT TO BOARD REVIEW, INCLUDING THE RESULTS OF THE REVIEW AND THE**
 27 **NUMBER AND DISPOSITION OF APPEALS AND JUDICIAL REVIEWS OF BOARD**
 28 **DECISIONS; AND**

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

1 ~~6-226.~~

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

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

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

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

12 ~~AND~~

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

14 SECTION 2. AND BE IT FURTHER ENACTED, That:

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

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

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

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

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

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

24 (2) ~~seven~~ eight members in 2023; and

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

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

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

- 1 (i) the prices of generic drugs on a year-over-year basis;
- 2 (ii) the degree to which generic drug prices affect yearly insurance
3 premium changes;
- 4 (iii) annual changes in insurance cost-sharing for generic drugs;
- 5 (iv) the potential for and history of drug shortages;
- 6 (v) the degree to which generic drug prices affect yearly State
7 Medicaid spending; and
- 8 (vi) any other relevant study questions; and
- 9 (2) report its findings to the General Assembly, in accordance with §
10 2-1246 of the State Government Article.

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

- 18 (1) monitor and assess the impact of upper payment limits and policy
19 actions by the Prescription Drug Affordability Board on:
- 20 (i) prescription drug affordability and access to hospital services in
21 the State;
- 22 (ii) the ability of hospitals and other providers to obtain drugs from
23 manufacturers and suppliers at costs consistent with the upper payment limits established
24 by the Board; and
- 25 (iii) the ability of the State to meet the requirements of the All-Payer
26 Model Contract; and
- 27 (2) report its findings and recommendations to the General Assembly, in
28 accordance with § 2-1246 of the State Government Article.

29 SECTION 5. AND BE IT FURTHER ENACTED, That, on or before December 1,
30 2023, the Prescription Drug Affordability Board established under § 21-2C-02 of the
31 Health – General Article, as enacted by Section 1 of this Act, in consultation with the
32 Prescription Drug Affordability Stakeholder Council established under § 21-2C-04 of the
33 Health – General Article, as enacted by Section 1 of this Act, shall report to the Senate

1 Finance Committee and the House Health and Government Operations Committee, in
 2 accordance with § 2–1246 of the State Government Article, on:

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

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

8 SECTION 6. AND BE IT FURTHER ENACTED, That, on or before December 1,
 9 2020, the State Designated Health Information Exchange and the Prescription Drug
 10 Affordability Board established under § 21–2C–02 of the Health – General Article, as
 11 enacted by Section 1 of this Act, jointly shall:

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

14 (2) report their findings and recommendations, including any necessary
 15 statutory changes, to the General Assembly, in accordance with § 2–1246 of the State
 16 Government Article.

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

22 SECTION ~~6~~ 8. AND BE IT FURTHER ENACTED, That this Act shall take effect
 23 ~~October~~ July 1, 2019.

Approved:

Governor.

Speaker of the House of Delegates.

President of the Senate.