

HOUSE BILL 424

J1, J5

(5lr2044)

ENROLLED BILL

— Health and Government Operations/Finance —

Introduced by Delegates Cullison and ~~White Holland~~, White Holland, Alston, Bagnall, Bhandari, Guzzone, Hill, S. Johnson, Kaiser, Kerr, Lopez, Martinez, Pena-Melnyk, Rosenberg, Taveras, Woods, and Woorman

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 **Prescription Drug Affordability Board – Authority ~~for Upper Payment Limits~~**
3 **and Stakeholder Council Membership**
4 **(Lowering Prescription Drug Costs for All Marylanders Now Act)**

5 FOR the purpose of *altering the membership of the Prescription Drug Affordability*
6 *Stakeholder Council*; requiring the Prescription Drug Affordability Board, under
7 certain circumstances, to establish a process for setting upper payment limits for ~~all~~
8 purchases and payor reimbursements of prescription drug products in the State that
9 the Board determines have led or will lead to affordability challenges; authorizing
10 the Board to reconsider an upper payment limit for a drug that becomes a current
11 shortage; altering requirements related to the setting of upper payment limits by the
12 Board; requiring the Board to confer with the Maryland Medical Assistance Program
13 before establishing an upper payment limit that applies to the Program; prohibiting

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 the Board from taking certain actions related to upper payment limits; and generally
2 relating to the Prescription Drug Affordability Board.

3 BY repealing and reenacting, with amendments,
4 Article – Health – General
5 Section 21–2C–01, ~~21–2C–04~~, 21–2C–13, and 21–2C–14
6 Annotated Code of Maryland
7 (2023 Replacement Volume and 2024 Supplement)

8 BY repealing and reenacting, without amendments,
9 Article – Health – General
10 Section 21–2C–09(c) and 21–2C–11(a)
11 Annotated Code of Maryland
12 (2023 Replacement Volume and 2024 Supplement)

13 BY adding to
14 Article – Health – General
15 Section 21–2C–09(d) and (e) and 21–2C–16
16 Annotated Code of Maryland
17 (2023 Replacement Volume and 2024 Supplement)

18 BY repealing
19 Article – Health – General
20 Section 21–2C–11(d) and 21–2C–16
21 Annotated Code of Maryland
22 (2023 Replacement Volume and 2024 Supplement)

23 ~~BY adding to~~
24 ~~Article – Health – General~~
25 ~~Section 21–2C–16~~
26 ~~Annotated Code of Maryland~~
27 ~~(2023 Replacement Volume and 2024 Supplement)~~

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

30 **Article – Health – General**

31 21–2C–01.

32 (a) In this subtitle the following words have the meanings indicated.

33 (b) “Biologic” means a drug that is produced or distributed in accordance with a
34 biologics license application approved under 42 C.F.R. § 447.502.

35 (c) “Biosimilar” means a drug that is produced or distributed in accordance with
36 a biologics license application approved under 42 U.S.C. § 262(k)(3).

1 (d) “Board” means the Prescription Drug Affordability Board.

2 (e) (1) “Brand name drug” means a drug that is produced or distributed in
3 accordance with an original new drug application approved under 21 U.S.C. § 355(c).

4 (2) “Brand name drug” does not include an authorized generic as defined
5 by 42 C.F.R. § 447.502.

6 (F) “CURRENT SHORTAGE” MEANS A DRUG:

7 (1) LISTED AS CURRENT ON THE FEDERAL FOOD AND DRUG
8 ADMINISTRATION’S DRUG SHORTAGE DATABASE; OR

9 (2) OTHERWISE DETERMINED BY THE BOARD TO BE IN SHORT
10 SUPPLY IN THE STATE.

11 [(f)] (G) “Generic drug” means:

12 (1) A retail drug that is marketed or distributed in accordance with an
13 abbreviated new drug application, approved under 21 U.S.C. § 355(j);

14 (2) An authorized generic as defined by 42 C.F.R. § 447.502; or

15 (3) A drug that entered the market before 1962 that was not originally
16 marketed under a new drug application.

17 [(g)] (H) “Manufacturer” means an entity that:

18 (1) (i) Engages in the manufacture of a prescription drug product; or

19 (ii) Enters into a lease with another manufacturer to market and
20 distribute a prescription drug product under the entity’s own name; and

21 (2) Sets or changes the wholesale acquisition cost of the prescription drug
22 product it manufactures or markets.

23 [(h)] (I) “Prescription drug product” means a brand name drug, a generic drug,
24 a biologic, or a biosimilar.

25 [(i)] (J) “Stakeholder Council” means the Prescription Drug Affordability
26 Stakeholder Council.

27 21-2C-04.

28 (a) There is a Prescription Drug Affordability Stakeholder Council.

1 **(b)** *The purpose of the Stakeholder Council is to provide stakeholder input to assist*
 2 *the Board in making decisions as required under this subtitle.*

3 **(c)** **(1)** *The Stakeholder Council consists of [26] members appointed in*
 4 *accordance with this subsection.*

5 **(2)** *The Speaker of the House of Delegates shall appoint:*

6 **(i)** *One representative of generic drug corporations;*

7 **(ii)** *One representative of nonprofit insurance carriers;*

8 **(iii)** *One representative of a statewide health care advocacy coalition;*

9 **(iv)** *One representative of a statewide advocacy organization for*
 10 *seniors;*

11 **(v)** *One representative of a statewide organization for diverse*
 12 *communities;*

13 **(vi)** *One representative of a labor union;*

14 **(vii)** **ONE REPRESENTATIVE OF THE RARE DISEASE COMMUNITY;**

15 **(VIII)** *One health services researcher specializing in prescription drugs;*

16 *and*

17 **[(viii)] (IX)** *One public member at the discretion of the Speaker of the*
 18 *House of Delegates.*

19 **(3)** *The President of the Senate shall appoint:*

20 **(i)** *One representative of brand name drug corporations;*

21 **(ii)** *One representative of physicians;*

22 **(iii)** *One representative of nurses;*

23 **(iv)** *One representative of hospitals;*

24 **(v)** *One representative of dentists;*

25 **(vi)** **ONE REPRESENTATIVE OF ONCOLOGISTS;**

26 **(VII)** *One representative of managed care organizations;*

1 [(vii)] (VIII) One representative of the Department of Budget and
 2 Management;

3 [(viii)] (IX) One clinical researcher; and

4 [(ix)] (X) One public member at the discretion of the President of the
 5 Senate.

6 (4) The Governor shall appoint:

7 (i) One representative of brand name drug corporations;

8 (ii) One representative of generic drug corporations;

9 (iii) One representative of biotechnology companies;

10 (iv) One representative of for-profit health insurance carriers;

11 (v) One representative of employers;

12 (vi) One representative of pharmacy benefits managers;

13 (vii) One representative of pharmacists;

14 (viii) One pharmacologist; [and]

15 (ix) ONE REPRESENTATIVE OF A PATIENT ADVOCACY
 16 ORGANIZATION; AND

17 (X) One public member at the discretion of the Governor.

18 (5) Collectively, the members of the Stakeholder Council shall have
 19 knowledge of the following:

20 (i) The pharmaceutical business model;

21 (ii) Supply chain business models;

22 (iii) The practice of medicine or clinical training;

23 (iv) Consumer or patient perspectives;

24 (v) Health care costs trends and drivers;

25 (vi) Clinical and health services research; or

1 (vii) The State's health care marketplace.

2 (6) To the extent practicable and consistent with federal and State law, the
3 membership of the Stakeholder Council shall reflect the racial, ethnic, and gender diversity
4 of the State.

5 (7) From among the membership of the Stakeholder Council, the Board
6 chair shall appoint two members to be cochairs of the Stakeholder Council.

7 (d) (1) The term of a member is 3 years.

8 (2) The initial members of the Stakeholder Council shall serve staggered
9 terms as required by the terms provided for members on October 1, 2019.

10 (e) A member of the Stakeholder Council:

11 (1) May not receive compensation as a member of the Stakeholder Council;
12 but

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

15 21-2C-09.

16 (c) On or before December 31, 2020, and each December 31 thereafter, the Board
17 shall submit to the Senate Finance Committee and the House Health and Government
18 Operations Committee, in accordance with § 2-1257 of the State Government Article, a
19 report that includes:

20 (1) Price trends for prescription drug products;

21 (2) The number of prescription drug products that were subject to Board
22 review and the results of the review; and

23 (3) Any recommendations the Board may have on further legislation needed
24 to make prescription drug products more affordable in the State.

25 (D) IF THE BOARD SETS A NEW UPPER PAYMENT LIMIT, TO THE EXTENT
26 PRACTICABLE, THE BOARD SHALL INCLUDE IN THE FIRST REPORT THAT IS
27 REQUIRED UNDER SUBSECTION (C) OF THIS SECTION AFTER THE UPPER PAYMENT
28 LIMIT HAS BEEN IN EFFECT FOR 1 YEAR INFORMATION ON THE EFFECTS OF THE
29 UPPER PAYMENT LIMIT, BASED ON AVAILABLE TIMELY DATA, FOR THE FOLLOWING:

1 (1) PATIENT OUT-OF-POCKET COSTS INCLUDING WHETHER THE
2 UPPER PAYMENT LIMIT WAS ASSOCIATED WITH INCREASES OR DECREASES IN WHAT
3 PATIENTS PAY FOR PRESCRIPTION DRUG PRODUCTS;

4 (2) PATIENT HEALTH INSURANCE PREMIUMS, INCLUDING WHETHER
5 THE UPPER PAYMENT LIMIT IS ASSOCIATED WITH INCREASES OR DECREASES IN
6 HEALTH INSURANCE COSTS FOR PATIENTS;

7 (3) PHARMACIES OPERATING IN THE STATE, INCLUDING THE IMPACT
8 ON REIMBURSEMENT RATES AND FINANCIAL VIABILITY OF RETAIL AND
9 INDEPENDENT PHARMACIES;

10 (4) PATIENT HEALTH INSURANCE FORMULARIES, INCLUDING
11 WHETHER THE PRESCRIPTION DRUG PRODUCT SUBJECT TO THE UPPER PAYMENT
12 LIMIT REMAINED ON FORMULARIES;

13 (5) PROVIDER-ADMINISTERED MEDICATIONS SUBJECT TO THE
14 UPPER PAYMENT LIMIT, INCLUDING WHETHER PROVIDERS WERE ABLE TO ACQUIRE
15 THE PRESCRIPTION DRUG PRODUCT SUBJECT TO THE UPPER PAYMENT LIMIT AT A
16 RATE TO ACCOUNT FOR ACQUISITION COSTS AND WHETHER THERE WAS AN IMPACT
17 ON PROVIDER REIMBURSEMENT;

18 (6) PATIENT ACCESS TO THE PRESCRIPTION DRUG PRODUCT
19 SUBJECT TO THE UPPER PAYMENT LIMIT, WHICH MAY INCLUDE:

20 (I) WHETHER PRESCRIPTION DRUG PRODUCT SHORTAGES OR
21 OTHER SUPPLY DISRUPTIONS OCCURRED AFTER THE UPPER PAYMENT LIMIT TOOK
22 EFFECT;

23 (II) WHETHER FORMULARY PLACEMENT OR PLAN DESIGN
24 CHANGES MADE THE PRESCRIPTION DRUG PRODUCT SUBJECT TO THE UPPER LIMIT
25 MORE DIFFICULT FOR PATIENTS TO ACCESS, INCLUDING IF INSURANCE PLANS
26 PREFERRED A PRESCRIPTION DRUG PRODUCT WITHOUT AN UPPER PAYMENT LIMIT
27 OVER A PRESCRIPTION DRUG PRODUCT SUBJECT TO AN UPPER PAYMENT LIMIT;

28 (III) WHETHER THE DISTRIBUTION AND DELIVERY OF SPECIALTY
29 OR RARE DISEASE MEDICATIONS FROM OUT-OF-STATE PHARMACIES TO PROVIDERS,
30 PHARMACIES, OR PATIENTS WAS IMPACTED;

31 (IV) WHETHER PATIENTS IN COMMUNITIES OF COLOR, PATIENTS
32 WHO ARE WOMEN, PATIENTS WITH A RARE DISEASE, OR PATIENTS IN RURAL AREAS
33 EXPERIENCED DISPROPORTIONATE ACCESS CHALLENGES; AND

1 (V) WHETHER COST DIFFERENCES AS A RESULT OF THE UPPER
 2 PAYMENT LIMIT AFFECTED PATIENTS, PHARMACIES, OR PROVIDERS AND, IF THE
 3 COST DIFFERENCE RESULTED IN AN INCREASE IN COSTS, WHO WAS ULTIMATELY
 4 RESPONSIBLE FOR BEARING THE INCREASED COST;

5 (7) COVERED ENTITY PROVIDERS PARTICIPATING IN THE 340B DRUG
 6 DISCOUNT PROGRAM, INCLUDING THE IMPACT OF THE UPPER PAYMENT LIMIT ON
 7 THE OPERATIONS OF THE PROVIDERS AND THEIR CONTRACTED PHARMACIES; AND

8 (8) THE BIOTECHNOLOGY INDUSTRY IN THE STATE, INCLUDING THE
 9 IMPACT ON PHARMACEUTICAL RESEARCH AND DEVELOPMENT, INVESTMENT, AND
 10 JOB GROWTH.

11 (E) (1) THE BOARD MAY REQUEST INFORMATION NECESSARY TO
 12 COMPLETE THE REPORT REQUIRED UNDER SUBSECTIONS (C) AND (D) OF THIS
 13 SECTION FROM AN AFFECTED ENTITY.

14 (2) THE ENTITY FROM WHICH INFORMATION WAS REQUESTED UNDER
 15 PARAGRAPH (1) OF THIS SUBSECTION SHALL MAKE A GOOD FAITH EFFORT TO
 16 PROVIDE THE REQUESTED INFORMATION.

17 21-2C-11.

18 (a) In this section, "Fund" means the Prescription Drug Affordability Fund.

19 [(d) (1) The Board shall be established using special or general funds, which
 20 shall be repaid to the State with the funds from the Fund.

21 (2) If the Board receives funding from the Maryland Health Care
 22 Commission under paragraph (1) of this subsection, the Board shall repay the funds to the
 23 Commission from the Fund over a 3-year period beginning June 1, 2021.]

24 21-2C-13.

25 (a) If, under § 21-2C-07 of this subtitle, the Board finds that it is in the best
 26 interest of the State to establish a process for setting upper payment limits for prescription
 27 drug products that it determines have led or will lead to an affordability challenge, the
 28 Board, in conjunction with the Stakeholder Council, shall draft a plan of action for
 29 implementing the process [that includes the criteria the Board shall use to set upper
 30 payment limits] **IN ACCORDANCE WITH THE REQUIREMENTS OF THIS SECTION.**

31 (b) The criteria for setting upper payment limits shall include consideration of:

32 (1) The cost of administering the prescription drug product;

1 (2) The cost of delivering the prescription drug product to consumers; [and]

2 (3) **THE EFFECT THE UPPER PAYMENT LIMIT WILL HAVE ON**
3 **PROVIDERS OF 340B DRUGS;**

4 (4) **FOR AN UPPER PAYMENT LIMIT ON A DRUG THAT IS DESIGNATED**
5 **AS A DRUG FOR A RARE DISEASE OR CONDITION, THE IMPACT OF THE UPPER**
6 **PAYMENT LIMIT ON PATIENTS WITH RARE DISEASES; AND**

7 [(3)] ~~(4)~~ (5) Other relevant administrative costs related to the prescription
8 drug product.

9 [(c)] The process for setting upper payment limits shall:

10 (1) Prohibit the application of an upper payment limit for a prescription
11 drug product that is on the federal Food and Drug Administration prescription drug
12 shortage list; and

13 (2) Require the Board to:

14 (i) Monitor the availability of any prescription drug product for
15 which it sets an upper payment limit; and

16 (ii) If there becomes a shortage of the prescription drug product in
17 the State, reconsider or suspend the upper payment limit.]

18 (c) (1) **IF THE BOARD PREVIOUSLY SET AN UPPER PAYMENT LIMIT FOR A**
19 **DRUG THAT BECOMES A CURRENT SHORTAGE, THE BOARD MAY RECONSIDER THE**
20 **PREVIOUSLY SET UPPER PAYMENT LIMIT.**

21 (2) **THE BOARD MAY NOT:**

22 (i) ~~ESTABLISH~~ **APPLY** A NEW UPPER PAYMENT LIMIT ~~FOR~~ **TO A**
23 **DRUG IN** A CURRENT SHORTAGE;

24 (ii) **ENFORCE AN UPPER PAYMENT LIMIT AGAINST PROVIDER**
25 **OR PHARMACY REIMBURSEMENT REQUIREMENTS FOR MEDICARE PART C OR PART**
26 **D PLANS; OR**

27 (iii) **COUNT A PHARMACY DISPENSING FEE TOWARD OR**
28 **SUBJECT A PHARMACY DISPENSING FEE TO AN UPPER PAYMENT LIMIT.**

1 (d) (1) If a plan of action is drafted under subsection (a) of this section, the
2 Board shall submit the plan of action to the Legislative Policy Committee of the General
3 Assembly, in accordance with § 2–1257 of the State Government Article, for its approval.

4 (2) The Legislative Policy Committee shall have 45 days to approve the
5 plan of action.

6 (3) If the Legislative Policy Committee does not approve the plan of action,
7 the Board shall submit the plan to the Governor and the Attorney General for approval.

8 (4) The Governor and the Attorney General shall have 45 days to approve
9 the plan of action.

10 (5) The Board may not set upper payment limits unless the plan is
11 approved, in accordance with this subsection, by:

12 (i) The Legislative Policy Committee; or

13 (ii) 1. The Governor; and

14 2. The Attorney General.

15 21–2C–14.

16 [(a) If a plan of action is approved under § 21–2C–13(d) of this subtitle] **IN**
17 **ACCORDANCE WITH THE PLAN OF ACTION APPROVED BY THE LEGISLATIVE POLICY**
18 **COMMITTEE ON OCTOBER 22, 2024**, the Board may set upper payment limits ***THROUGH***
19 ***REGULATIONS*** for prescription drug products that are:

20 (1) Purchased or paid for by a unit of State or local government or an
21 organization on behalf of a unit of State or local government, including:

22 (i) State or county correctional facilities;

23 (ii) State hospitals; and

24 (iii) Health clinics at State institutions of higher education;

25 (2) Paid for through a health benefit plan on behalf of a unit of State or
26 local government, including a county, bicounty, or municipal employee health benefit plan;
27 or

28 (3) Purchased for or paid for by the Maryland State Medical Assistance
29 Program.

30 [(b) The upper payment limits set under subsection (a) of this section shall:

1 (1) Be for prescription drug products that have led or will lead to an
2 affordability challenge; and

3 (2) Be set in accordance with the criteria established in regulations
4 adopted by the Board.

5 (c) (1) The Board shall:

6 (i) Monitor the availability of any prescription drug product for
7 which it sets an upper payment limit; and

8 (ii) If there becomes a shortage of the prescription drug product in
9 the State, reconsider whether the upper payment limit should be suspended or altered.

10 (2) An upper payment limit set under subsection (a) of this section may not
11 be applied to a prescription drug product while the prescription drug product is on the
12 federal Food and Drug Administration prescription drug shortage list.]

13 [21-2C-16.

14 On or before December 1, 2026, the Board, in consultation with the Stakeholder
15 Council, shall report to the Senate Finance Committee and the House Health and
16 Government Operations Committee, in accordance with § 2-1257 of the State Government
17 Article, on:

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

20 (2) Recommendations regarding whether the General Assembly should
21 pass legislation to expand the authority of the Board to set upper payment limits to all
22 purchases and payor reimbursements of prescription drug products in the State.]

23 **21-2C-16.**

24 **(A) (1) THE BOARD, IN CONSULTATION WITH THE STAKEHOLDER**
25 **COUNCIL, SHALL DETERMINE WHETHER, IN ADDITION TO SETTING UPPER PAYMENT**
26 **LIMITS IN ACCORDANCE WITH § 21-2C-14 OF THIS SUBTITLE, IT IS IN THE BEST**
27 **INTEREST OF THE STATE FOR THE BOARD TO ESTABLISH A PROCESS FOR SETTING**
28 **UPPER PAYMENT LIMITS FOR ~~ALL~~ PURCHASES AND PAYOR REIMBURSEMENTS OF**
29 **PRESCRIPTION DRUG PRODUCTS IN THE STATE THAT THE BOARD DETERMINES**
30 **HAVE LED OR WILL LEAD TO AN AFFORDABILITY CHALLENGE.**

31 **(2) WHEN MAKING A DETERMINATION UNDER PARAGRAPH (1) OF**
32 **THIS SUBSECTION, THE BOARD SHALL CONSIDER, IF APPLICABLE:**

1 (I) CONTRACT AND BUDGET DATA PROVIDED TO THE BOARD
2 THAT DEMONSTRATES SAVINGS TO THE STATE OR LOCAL GOVERNMENTS AS A
3 RESULT OF UPPER PAYMENT LIMITS SET IN ACCORDANCE WITH § 21-2C-14 OF THIS
4 SUBTITLE;

5 (II) SUCCESS OF SETTING UPPER PAYMENT LIMITS IN OTHER
6 STATES; AND

7 (III) EXPECTED SAVINGS FROM MEDICARE MAXIMUM FAIR
8 PRICES SET BY THE CENTERS FOR MEDICARE AND MEDICAID SERVICES.

9 (B) (1) IF THE BOARD MAKES AN AFFIRMATIVE DETERMINATION UNDER
10 SUBSECTION (A) OF THIS SECTION, THE BOARD, IN CONSULTATION WITH THE
11 STAKEHOLDER COUNCIL, SHALL ESTABLISH A PROCESS FOR SETTING UPPER
12 PAYMENT LIMITS FOR ~~ALL~~ PURCHASES AND PAYOR REIMBURSEMENTS OF
13 PRESCRIPTION DRUG PRODUCTS IN THE STATE THAT THE BOARD DETERMINES
14 HAVE LED OR WILL LEAD TO AN AFFORDABILITY CHALLENGE.

15 (2) THE PROCESS ESTABLISHED UNDER PARAGRAPH (1) OF THIS
16 SUBSECTION SHALL:

17 (I) TO THE EXTENT APPROPRIATE, USE THE PLAN OF ACTION
18 APPROVED UNDER § 21-2C-13(D) OF THIS SUBTITLE; AND

19 (II) OTHERWISE COMPLY WITH THE REQUIREMENTS FOR
20 SETTING UPPER PAYMENT LIMITS ESTABLISHED UNDER THIS SUBTITLE.

21 (3) BEFORE ESTABLISHING AN UPPER PAYMENT LIMIT THAT APPLIES
22 TO THE MARYLAND MEDICAL ASSISTANCE PROGRAM, THE BOARD SHALL CONFER
23 WITH THE MARYLAND MEDICAL ASSISTANCE PROGRAM TO APPROVE THE
24 APPLICATION OF THE UPPER PAYMENT LIMIT BY ASSESSING WHETHER THE
25 PROPOSED UPPER PAYMENT LIMIT WILL:

26 (I) CONFLICT WITH THE MEDICAID DRUG REBATES
27 PROGRAM, THE COVERED OUTPATIENT DRUG RULE (CMS-2345-FC), OR ANY
28 OTHER FEDERAL REQUIREMENTS AS APPLICABLE; AND

29 (II) REQUIRE ADDITIONAL FUNDING TO BE ALLOCATED TO THE
30 MARYLAND MEDICAL ASSISTANCE PROGRAM BUDGET.

31 SECTION 2. AND BE IT FURTHER ENACTED, That the Laws of Maryland read
32 as follows:

1 Article – Health – General

2 21–2C–16.

3 (C) (1) ~~IF SUBJECT TO PARAGRAPH (2) OF THIS SUBSECTION, IF THE~~
 4 BOARD ESTABLISHES A PROCESS UNDER SUBSECTION (B) OF THIS SECTION, THE
 5 BOARD SHALL SET UPPER PAYMENT LIMITS FOR ~~ALL~~ PURCHASES AND PAYOR
 6 REIMBURSEMENTS OF PRESCRIPTION DRUG PRODUCTS IN THE STATE IN
 7 ACCORDANCE WITH THE PROCESS.

8 (2) THIS SUBSECTION DOES NOT APPLY WITH RESPECT TO:

9 (I) PAYOR REIMBURSEMENTS UNDER MEDICARE PART C AND
 10 D PLANS;

11 (II) PURCHASES UNDER THE FEDERAL 340B DRUG PRICING
 12 PROGRAM; AND

13 (III) PURCHASES AND PAYOR REIMBURSEMENTS UNDER BY
 14 FEDERAL AGENCIES OR FEDERAL PROGRAMS THAT ARE THE STATE IS PREEMPTED
 15 FROM REGULATING BY FEDERAL LAW INCLUDING:

16 ~~1. THE DEPARTMENT OF DEFENSE;~~

17 ~~2. THE DEPARTMENT OF VETERANS AFFAIRS;~~

18 ~~3. THE PUBLIC HEALTH SERVICE;~~

19 ~~4. THE UNITED STATES COAST GUARD;~~

20 ~~5. TRICARE;~~

21 ~~6. THE FEDERAL EMPLOYEES HEALTH BENEFIT PLAN;~~

22 AND

23 ~~7. ANY OTHER EXCLUSIVE FEDERAL PROGRAM AS~~

24 APPLICABLE.

25 SECTION 3. AND BE IT FURTHER ENACTED, That:

26 (a) Section 2 of this Act is contingent on the Prescription Drug Affordability Board
 27 setting upper payment limits on two prescription drugs in accordance with § 21–2C–14 of

1 the Health – General Article, as enacted by Section 1 of this Act, and each upper payment
2 limit being in effect for 1 year.

3 (b) Within 5 days after the conditions described in subsection (a) of this section
4 are met, the Prescription Drug Affordability Board shall notify the Department of
5 Legislative Services.

6 (c) If notice is received by the Department of Legislative Services in accordance
7 with subsection (b) of this section on or before ~~September 31~~ September 30, 2030, Section 2
8 of this Act shall take effect on the date the notice is received by the Department of
9 Legislative Services.

10 (d) If notice is not received by the Department of Legislative Services on or before
11 ~~December 31~~ September 30, 2030, Section 2 of this Act, with no further action required by
12 the General Assembly, shall be null and void.

13 SECTION 4. AND BE IT FURTHER ENACTED, That, subject to Section 3 of this
14 Act, this Act shall take effect October 1, 2025.

Approved:

Governor.

Speaker of the House of Delegates.

President of the Senate.