

SENATE BILL 357

J1, J5

5lr2092
CF HB 424

By: **Senators Gile and Feldman**

Introduced and read first time: January 16, 2025

Assigned to: Finance

A BILL ENTITLED

1 AN ACT concerning

2 **Prescription Drug Affordability Board – Authority for Upper Payment Limits**
3 **(Lowering Prescription Drug Costs for All Marylanders Now Act)**

4 FOR the purpose of requiring the Prescription Drug Affordability Board, under certain
5 circumstances, to establish a process for setting upper payment limits for all
6 purchases and payor reimbursements of prescription drug products in the State that
7 the Board determines have led or will lead to affordability challenges; authorizing
8 the Board to reconsider an upper payment limit for a drug that becomes a current
9 shortage; altering requirements related to the setting of upper payment limits by the
10 Board; prohibiting the Board from taking certain actions related to upper payment
11 limits; and generally relating to the Prescription Drug Affordability Board.

12 BY repealing and reenacting, with amendments,
13 Article – Health – General
14 Section 21–2C–01, 21–2C–13, and 21–2C–14
15 Annotated Code of Maryland
16 (2023 Replacement Volume and 2024 Supplement)

17 BY repealing and reenacting, without amendments,
18 Article – Health – General
19 Section 21–2C–11(a)
20 Annotated Code of Maryland
21 (2023 Replacement Volume and 2024 Supplement)

22 BY repealing
23 Article – Health – General
24 Section 21–2C–11(d) and 21–2C–16
25 Annotated Code of Maryland
26 (2023 Replacement Volume and 2024 Supplement)

27 BY adding to

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 Article – Health – General
2 Section 21–2C–16
3 Annotated Code of Maryland
4 (2023 Replacement Volume and 2024 Supplement)

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

7 **Article – Health – General**

8 21–2C–01.

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

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

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

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

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

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

19 **(F) “CURRENT SHORTAGE” MEANS A DRUG:**

20 **(1) LISTED AS CURRENT ON THE FEDERAL FOOD AND DRUG**
21 **ADMINISTRATION’S DRUG SHORTAGE DATABASE; OR**

22 **(2) OTHERWISE DETERMINED BY THE BOARD TO BE IN SHORT**
23 **SUPPLY IN THE STATE.**

24 **[(f)] (G)** “Generic drug” means:

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

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

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

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

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

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

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

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

9 **[(i)] (J)** “Stakeholder Council” means the Prescription Drug Affordability
10 Stakeholder Council.

11 21–2C–11.

12 (a) In this section, “Fund” means the Prescription Drug Affordability Fund.

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

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

18 21–2C–13.

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

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

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

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

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

1 ~~[(3)]~~ (4) Other relevant administrative costs related to the prescription
2 drug product.

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

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

7 (2) Require the Board to:

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

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

12 **(C) (1) IF THE BOARD PREVIOUSLY SET AN UPPER PAYMENT LIMIT FOR A**
13 **DRUG THAT BECOMES A CURRENT SHORTAGE, THE BOARD MAY RECONSIDER THE**
14 **PREVIOUSLY SET UPPER PAYMENT LIMIT.**

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

16 **(I) ESTABLISH A NEW UPPER PAYMENT LIMIT FOR A CURRENT**
17 **SHORTAGE;**

18 **(II) ENFORCE AN UPPER PAYMENT LIMIT AGAINST PROVIDER**
19 **OR PHARMACY REIMBURSEMENT REQUIREMENTS FOR MEDICARE PART C OR PART**
20 **D PLANS; OR**

21 **(III) COUNT A PHARMACY DISPENSING FEE TOWARD OR**
22 **SUBJECT A PHARMACY DISPENSING FEE TO AN UPPER PAYMENT LIMIT.**

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

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

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

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

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

3 (i) The Legislative Policy Committee; or

4 (ii) 1. The Governor; and

5 2. The Attorney General.

6 21-2C-14.

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

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

13 (i) State or county correctional facilities;

14 (ii) State hospitals; and

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

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

19 (3) Purchased for or paid for by the Maryland State Medical Assistance
20 Program.

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

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

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

26 (c) (1) The Board shall:

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

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

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

6 [21-2C-16.

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

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

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

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

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

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

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

30 **(II) SUCCESS OF SETTING UPPER PAYMENT LIMITS IN OTHER**
31 **STATES; AND**

32 **(III) EXPECTED SAVINGS FROM MEDICARE MAXIMUM FAIR**
33 **PRICES SET BY THE CENTERS FOR MEDICARE AND MEDICAID SERVICES.**

1 **(B) (1) IF THE BOARD MAKES AN AFFIRMATIVE DETERMINATION UNDER**
2 **SUBSECTION (A) OF THIS SECTION, THE BOARD, IN CONSULTATION WITH THE**
3 **STAKEHOLDER COUNCIL, SHALL ESTABLISH A PROCESS FOR SETTING UPPER**
4 **PAYMENT LIMITS FOR ALL PURCHASES AND PAYOR REIMBURSEMENTS OF**
5 **PRESCRIPTION DRUG PRODUCTS IN THE STATE THAT THE BOARD DETERMINES**
6 **HAVE LED OR WILL LEAD TO AN AFFORDABILITY CHALLENGE.**

7 **(2) THE PROCESS ESTABLISHED UNDER PARAGRAPH (1) OF THIS**
8 **SUBSECTION SHALL:**

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

11 **(II) OTHERWISE COMPLY WITH THE REQUIREMENTS FOR**
12 **SETTING UPPER PAYMENT LIMITS ESTABLISHED UNDER THIS SUBTITLE.**

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

15 **Article – Health – General**

16 21-2C-16.

17 **(C) IF THE BOARD ESTABLISHES A PROCESS UNDER SUBSECTION (B) OF**
18 **THIS SECTION, THE BOARD SHALL SET UPPER PAYMENT LIMITS FOR ALL**
19 **PURCHASES AND PAYOR REIMBURSEMENTS OF PRESCRIPTION DRUG PRODUCTS IN**
20 **THE STATE IN ACCORDANCE WITH THE PROCESS.**

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

22 (a) Section 2 of this Act is contingent on the Prescription Drug Affordability Board
23 setting upper payment limits on two prescription drugs in accordance with § 21-2C-14 of
24 the Health – General Article, as enacted by Section 1 of this Act, and each upper payment
25 limit being in effect for 1 year.

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

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

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

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