

HOUSE BILL 340

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CF SB 388

By: **Delegates Cullison and White Holland**
Introduced and read first time: January 17, 2024
Assigned to: Health and Government Operations

A BILL ENTITLED

1 AN ACT concerning

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

5 FOR the purpose of requiring the Prescription Drug Affordability Board to make a certain
6 determination regarding the establishment of a process for setting upper payment
7 limits for all purchases and payor reimbursements of prescription drug products in
8 the State that the Board determines have led or will lead to an affordability
9 challenge; requiring the Board, under certain circumstances, to establish a process
10 for setting upper payment limits for all purchases and payor reimbursements of
11 prescription drug products in the State that the Board determines have led or will
12 lead to affordability challenges; altering the funding of the Board; and generally
13 relating to the Prescription Drug Affordability Board.

14 BY repealing and reenacting, with amendments,
15 Article – Health – General
16 Section 21–2C–11
17 Annotated Code of Maryland
18 (2023 Replacement Volume)

19 BY repealing and reenacting, without amendments,
20 Article – Health – General
21 Section 21–2C–13 and 21–2C–14
22 Annotated Code of Maryland
23 (2023 Replacement Volume)

24 BY repealing
25 Article – Health – General
26 Section 21–2C–16
27 Annotated Code of Maryland
28 (2023 Replacement Volume)

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.
[Brackets] indicate matter deleted from existing law.



1 BY adding to
2 Article – Health – General
3 Section 21–2C–16
4 Annotated Code of Maryland
5 (2023 Replacement Volume)

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

8 **Article – Health – General**

9 21–2C–11.

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

11 (b) (1) The Board shall assess and collect an annual fee on:

12 (i) Manufacturers that sell or offer for sale prescription drug
13 products to persons in the State;

14 (ii) Pharmacy benefits managers, as defined in § 15–1601 of the
15 Insurance Article;

16 (iii) Carriers, as defined in § 19–132 of this article; and

17 (iv) Wholesale distributors, as defined in § 12–6C–01 of the Health
18 Occupations Article, that sell or offer for sale prescription drug products to persons in the
19 State.

20 (2) The Board shall:

21 (i) Assess and collect the annual fee under paragraph (1) of this
22 subsection in accordance with criteria established in regulations adopted by the Board; and

23 (ii) Calculate the annual fee under paragraph (1) of this subsection
24 in a fair and equitable manner.

25 (3) (i) On or before October 1 each year, each entity assessed a fee
26 under this subsection shall pay the fee assessed by the Board.

27 (ii) The Board shall allow entities to make partial payments when
28 paying the fee assessed under this subsection.

29 (iii) Any fee not paid within 30 days after the payment due date may
30 be subject to an interest penalty to be determined and collected by the Board.

1 (4) The total amount of fees that the Board collects in each calendar year
2 under paragraph (1) of this subsection may not exceed \$2,000,000.

3 (5) The Board shall pay all fees collected under paragraph (1) of this
4 subsection into the Fund.

5 (c) (1) There is a Prescription Drug Affordability Fund.

6 (2) The purpose of the Fund is to provide funding for the Board and to carry
7 out the purpose of this subtitle.

8 (3) The Board shall administer the Fund.

9 (4) (i) The Fund is a special, nonlapsing fund that is not subject to §
10 7–302 of the State Finance and Procurement Article.

11 (ii) The State Treasurer shall hold the Fund separately, and the
12 Comptroller shall account for the Fund.

13 (5) The Fund consists of:

14 (i) Revenue distributed to the Fund under subsection (b) of this
15 section;

16 (ii) Money appropriated in the State budget to the Fund;

17 (iii) Interest earnings; and

18 (iv) Any other money from any other source accepted for the benefit
19 of the Fund.

20 (6) The Fund may be used only to provide funding for the Board and for the
21 purposes authorized under this subtitle, including administrative expenses and any costs
22 expended by any State agency to implement this subtitle.

23 (7) (i) The State Treasurer shall invest the money of the Fund in the
24 same manner as other State money may be invested.

25 (ii) Any interest earnings of the Fund shall be credited to the Fund.

26 (8) Expenditures from the Fund may be made only in accordance with the
27 State budget.

28 **(9) (I) FOR FISCAL YEAR 2025 AND EACH FISCAL YEAR**
29 **THEREAFTER, THE GOVERNOR SHALL INCLUDE IN THE ANNUAL BUDGET BILL AN**
30 **APPROPRIATION OF AT LEAST \$1,000,000 FOR THE FUND.**

1 **(II) EACH FISCAL YEAR, THE BOARD SHALL USE THE FUNDS**
2 **COLLECTED IN ACCORDANCE WITH SUBSECTION (B) OF THIS SECTION AND ANY**
3 **OTHER NON-STATE FUNDS IN THE FUND BEFORE USING THE MONEY**
4 **APPROPRIATED IN ACCORDANCE WITH SUBPARAGRAPH (I) OF THIS PARAGRAPH.**

5 **(10) NOTWITHSTANDING § 7-304 OF THE STATE FINANCE AND**
6 **PROCUREMENT ARTICLE, ANY UNSPENT PORTION OF THE FUND APPROPRIATED**
7 **UNDER PARAGRAPH (9)(I) OF THIS SUBSECTION:**

8 **(I) MAY NOT BE TRANSFERRED BY BUDGET AMENDMENT OR**
9 **OTHERWISE TO ANY OTHER FUND; AND**

10 **(II) SHALL REVERT TO THE GENERAL FUND.**

11 **[(9) (11)]** The Fund is subject to audit by the Office of Legislative Audits
12 as provided for under § 2-1220 of the State Government Article.

13 **[(10) (12)]** This subsection may not be construed to prohibit the Fund from
14 receiving funds from any other source.

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

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

20 21-2C-13.

21 (a) If, under § 21-2C-07 of this subtitle, the Board finds that it is in the best
22 interest of the State to establish a process for setting upper payment limits for prescription
23 drug products that it determines have led or will lead to an affordability challenge, the
24 Board, in conjunction with the Stakeholder Council, shall draft a plan of action for
25 implementing the process that includes the criteria the Board shall use to set upper
26 payment limits.

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

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

29 (2) The cost of delivering the prescription drug product to consumers; and

30 (3) Other relevant administrative costs related to the prescription drug
31 product.

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

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

4 (2) Require the Board to:

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

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

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

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

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

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

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

20 (i) The Legislative Policy Committee; or

21 (ii) 1. The Governor; and

22 2. The Attorney General.

23 21–2C–14.

24 (a) If a plan of action is approved under § 21–2C–13(d) of this subtitle, the Board
25 may set upper payment limits for prescription drug products that are:

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

28 (i) State or county correctional facilities;

29 (ii) State hospitals; and

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

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

5 (3) Purchased for or paid for by the Maryland State Medical Assistance
6 Program.

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

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

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

12 (c) (1) The Board shall:

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

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

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

20 [21-2C-16.

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

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

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

30 **21-2C-16.**

1 **(A) (1) ON OR AFTER OCTOBER 1, 2024, AND ONLY IF A PLAN OF ACTION**
2 **HAS BEEN APPROVED UNDER § 21-2C-13(D) OF THIS SUBTITLE, THE BOARD, IN**
3 **CONSULTATION WITH THE STAKEHOLDER COUNCIL, SHALL DETERMINE WHETHER,**
4 **IN ADDITION TO SETTING UPPER PAYMENT LIMITS IN ACCORDANCE WITH §**
5 **21-2C-14(A) OF THIS SUBTITLE, IT IS IN THE BEST INTEREST OF THE STATE FOR**
6 **THE BOARD TO ESTABLISH A PROCESS FOR SETTING UPPER PAYMENT LIMITS FOR**
7 **ALL PURCHASES AND PAYOR REIMBURSEMENTS OF PRESCRIPTION DRUG**
8 **PRODUCTS IN THE STATE THAT THE BOARD DETERMINES HAVE LED OR WILL LEAD**
9 **TO AN AFFORDABILITY CHALLENGE.**

10 **(2) WHEN MAKING A DETERMINATION UNDER PARAGRAPH (1) OF**
11 **THIS SUBSECTION, THE BOARD SHALL CONSIDER, IF AVAILABLE, CONTRACT AND**
12 **BUDGET DATA PROVIDED TO THE BOARD THAT DEMONSTRATES SAVINGS TO THE**
13 **STATE OR LOCAL GOVERNMENTS AS A RESULT OF UPPER PAYMENT LIMITS SET IN**
14 **ACCORDANCE WITH § 21-2C-14(A) OF THIS SUBTITLE.**

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

21 **(2) THE PROCESS ESTABLISHED UNDER PARAGRAPH (1) OF THIS**
22 **SUBSECTION SHALL:**

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

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

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

31 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
32 October 1, 2024.