J1, J5 CF HB 340

By: Senators Gile, Feldman, Beidle, Ellis, Guzzone, Hester, Hettleman, Jackson, Klausmeier, Kramer, and Lam

Introduced and read first time: January 18, 2024 Assigned to: Finance and Budget and Taxation

A BILL ENTITLED

2	Prescription Drug Affordability Board - Authority for Upper Payment Limits
3	and Funding

(Lowering Prescription Drug Costs for All Marylanders Act of 2024)

- 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

AN ACT concerning

- 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

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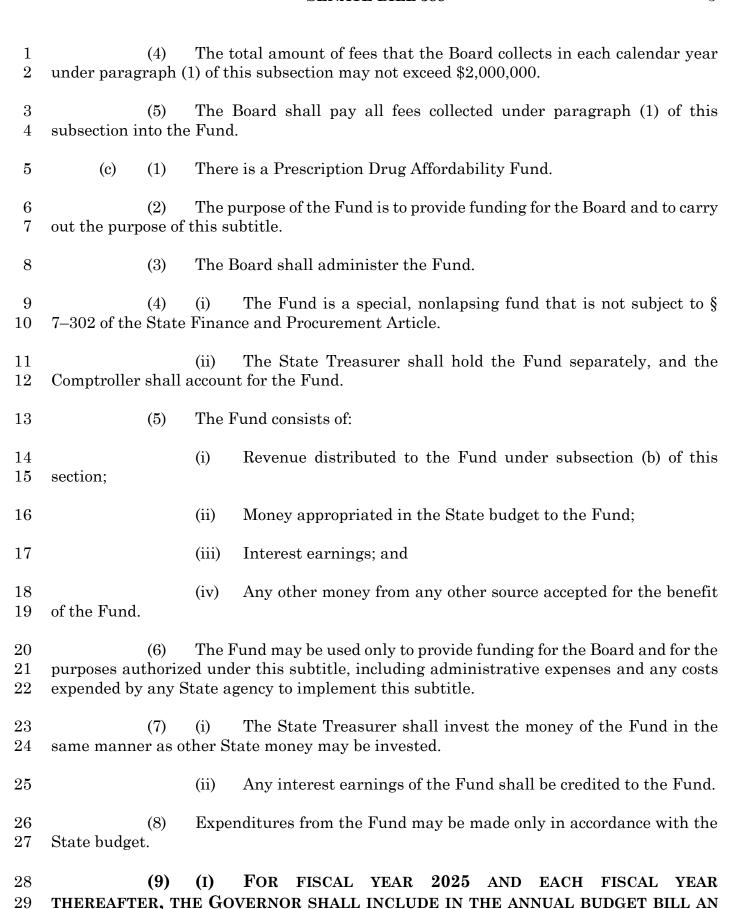
- 25 Article Health General
- 26 Section 21–2C–16
- 27 Annotated Code of Maryland

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1	(2023 Replacement Volume)
2 3 4 5 6	BY adding to Article – Health – General Section 21–2C–16 Annotated Code of Maryland (2023 Replacement Volume)
7 8	SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:
9	Article - Health - General
10	21–2C–11.
11	(a) In this section, "Fund" means the Prescription Drug Affordability Fund.
12	(b) (1) The Board shall assess and collect an annual fee on:
13 14	(i) Manufacturers that sell or offer for sale prescription drug products to persons in the State;
15 16	(ii) Pharmacy benefits managers, as defined in § 15–1601 of the Insurance Article;
17	(iii) Carriers, as defined in § 19–132 of this article; and
18 19 20	(iv) Wholesale distributors, as defined in § 12–6C–01 of the Health Occupations Article, that sell or offer for sale prescription drug products to persons in the State.
21	(2) The Board shall:
22 23	(i) Assess and collect the annual fee under paragraph (1) of this subsection in accordance with criteria established in regulations adopted by the Board; and
24 25	(ii) Calculate the annual fee under paragraph (1) of this subsection in a fair and equitable manner.
26 27	(3) (i) On or before October 1 each year, each entity assessed a fee under this subsection shall pay the fee assessed by the Board.
28 29	(ii) The Board shall allow entities to make partial payments when paying the fee assessed under this subsection.
30 31	(iii) Any fee not paid within 30 days after the payment due date may be subject to an interest penalty to be determined and collected by the Board.



APPROPRIATION OF AT LEAST \$1,000,000 FOR THE FUND.

product.

1 2 3 4	(II) EACH FISCAL YEAR, THE BOARD SHALL USE THE FUNDS COLLECTED IN ACCORDANCE WITH SUBSECTION (B) OF THIS SECTION AND ANY OTHER NON-STATE FUNDS IN THE FUND BEFORE USING THE MONEY APPROPRIATED IN ACCORDANCE WITH SUBPARAGRAPH (I) OF THIS PARAGRAPH.
5 6 7	(10) NOTWITHSTANDING § 7–304 OF THE STATE FINANCE AND PROCUREMENT ARTICLE, ANY UNSPENT PORTION OF THE FUND APPROPRIATED UNDER PARAGRAPH (9)(I) OF THIS SUBSECTION:
8 9	(I) MAY NOT BE TRANSFERRED BY BUDGET AMENDMENT OR OTHERWISE TO ANY OTHER FUND; AND
10	(II) SHALL REVERT TO THE GENERAL FUND.
11 12	[(9)] (11) The Fund is subject to audit by the Office of Legislative Audits as provided for under § 2–1220 of the State Government Article.
13 14	[(10)] (12) This subsection may not be construed to prohibit the Fund from receiving funds from any other source.
15 16	[(d) (1) The Board shall be established using special or general funds, which shall be repaid to the State with the funds from the Fund.
17 18 19	(2) If the Board receives funding from the Maryland Health Care Commission under paragraph (1) of this subsection, the Board shall repay the funds to the Commission from the Fund over a 3–year period beginning June 1, 2021.]
20	21–2C–13.
21 22 23 24 25 26	(a) If, under § 21–2C–07 of this subtitle, the Board finds that it is in the best interest of the State to establish a process for setting upper payment limits for prescription drug products that it determines have led or will lead to an affordability challenge, the Board, in conjunction with the Stakeholder Council, shall draft a plan of action for implementing the process that includes the criteria the Board shall use to set upper 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

1 (c) The process for setting upper payment limits shall: 2 Prohibit the application of an upper payment limit for a prescription 3 drug product that is on the federal Food and Drug Administration prescription drug shortage list; and 4 5 (2) Require the Board to: 6 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 or suspend the upper payment limit. 10 (d) (1)If a plan of action is drafted under subsection (a) of this section, the Board shall submit the plan of action to the Legislative Policy Committee of the General 11 12 Assembly, in accordance with § 2–1257 of the State Government Article, for its approval. 13 The Legislative Policy Committee shall have 45 days to approve the (2)plan of action. 14 15 If the Legislative Policy Committee does not approve the plan of action, the Board shall submit the plan to the Governor and the Attorney General for approval. 16 17 The Governor and the Attorney General shall have 45 days to approve **(4)** the plan of action. 18 19 (5)The Board may not set upper payment limits unless the plan is 20 approved, in accordance with this subsection, by: 21(i) The Legislative Policy Committee; or 22 (ii) 1. The Governor; and 23 2. The Attorney General. 24 21-2C-14. 25 If a plan of action is approved under § 21–2C–13(d) of this subtitle, the Board 26 may set upper payment limits for prescription drug products that are: 27 Purchased or paid for by a unit of State or local government or an 28 organization on behalf of a unit of State or local government, including: 29 (i) State or county correctional facilities;

State hospitals; and

(ii)

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 Purchased for or paid for by the Maryland State Medical Assistance 5 (3)6 Program. 7 (b) The upper payment limits set under subsection (a) of this section shall: 8 Be for prescription drug products that have led or will lead to an affordability challenge; and 9 10 (2)Be set in accordance with the criteria established in regulations 11 adopted by the Board. 12 (c) The Board shall: (1) 13 Monitor the availability of any prescription drug product for (i) which it sets an upper payment limit; and 14 15 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. **(2)** 17 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. 21On or before December 1, 2026, the Board, in consultation with the Stakeholder 22Council, 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 Article, on: 2425The 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 28pass legislation to expand the authority of the Board to set upper payment limits to all

purchases and payor reimbursements of prescription drug products in the State.

30 **21–2C–16.**

- ON OR AFTER OCTOBER 1, 2024, AND ONLY IF A PLAN OF ACTION 1 $(A) \quad (1)$ HAS BEEN APPROVED UNDER § 21-2C-13(D) OF THIS SUBTITLE, THE BOARD, IN 2 3 CONSULTATION WITH THE STAKEHOLDER COUNCIL, SHALL DETERMINE WHETHER, IN ADDITION TO SETTING UPPER PAYMENT LIMITS IN ACCORDANCE WITH § 4 21-2C-14(A) OF THIS SUBTITLE, IT IS IN THE BEST INTEREST OF THE STATE FOR 5 THE BOARD TO ESTABLISH A PROCESS FOR SETTING UPPER PAYMENT LIMITS FOR 6 7 ALL PURCHASES AND PAYOR REIMBURSEMENTS OF PRESCRIPTION DRUG PRODUCTS IN THE STATE THAT THE BOARD DETERMINES HAVE LED OR WILL LEAD 8 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.
- SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect 32 October 1, 2024.