SENATE BILL 202

J1, J5

EMERGENCY BILL

3lr1184 CF HB 279

By: Senator Feldman

Introduced and read first time: January 20, 2023 Assigned to: Finance

Committee Report: Favorable Senate action: Adopted Read second time: February 14, 2023

CHAPTER _____

1 AN ACT concerning

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Prescription Drug Affordability Board – Upper Payment Limits

3 FOR the purpose of reestablishing the requirement that the Prescription Drug Affordability 4 Board, under certain circumstances, draft a plan of action for implementing a process $\mathbf{5}$ to set upper payment limits for prescription drug products that it determines have 6 led or will lead to affordability challenges; reestablishing the authority of the Board 7 to set upper payment limits, under certain circumstances, for prescription drug 8 products that are purchased or paid for by or through certain State or local government entities, plans, or programs; reestablishing a certain appeals process for 9 10 persons aggrieved by an upper payment limit set by the Board; reestablishing the 11 requirement that the Board submit a report to certain committees of the General 12 Assembly recommending whether the General Assembly should expand the Board's 13authority to set upper payment limits to all purchases and payor reimbursements of 14 prescription drug products in the State; and generally relating to the setting of upper 15payment limits by the Prescription Drug Affordability Board.

- 16 BY adding to
- 17 Article Health General
- 18 Section 21–2C–13 through 21–2C–16
- 19 Annotated Code of Maryland
- 20 (2019 Replacement Volume and 2022 Supplement)
- 21 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND,
- 22 That the Laws of Maryland read as follows:

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.

<u>Underlining</u> indicates amendments to bill.

Strike out indicates matter stricken from the bill by amendment or deleted from the law by amendment.



Article – Health – General

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2 **21–2C–13.**

3 (A) IF, UNDER § 21–2C–07 OF THIS SUBTITLE, THE BOARD FINDS THAT IT IS 4 IN THE BEST INTEREST OF THE STATE TO ESTABLISH A PROCESS FOR SETTING 5 UPPER PAYMENT LIMITS FOR PRESCRIPTION DRUG PRODUCTS THAT IT 6 DETERMINES HAVE LED OR WILL LEAD TO AN AFFORDABILITY CHALLENGE, THE 7 BOARD, IN CONJUNCTION WITH THE STAKEHOLDER COUNCIL, SHALL DRAFT A PLAN 8 OF ACTION FOR IMPLEMENTING THE PROCESS THAT INCLUDES THE CRITERIA THE 9 BOARD SHALL USE TO SET UPPER PAYMENT LIMITS.

10 **(B)** THE CRITERIA FOR SETTING UPPER PAYMENT LIMITS SHALL INCLUDE 11 CONSIDERATION OF:

12 (1) THE COST OF ADMINISTERING THE PRESCRIPTION DRUG 13 PRODUCT;

14(2)THE COST OF DELIVERING THE PRESCRIPTION DRUG PRODUCT15TO CONSUMERS; AND

16 (3) OTHER RELEVANT ADMINISTRATIVE COSTS RELATED TO THE 17 PRESCRIPTION DRUG PRODUCT.

18 (C) THE PROCESS FOR SETTING UPPER PAYMENT LIMITS SHALL:

19(1) PROHIBIT THE APPLICATION OF AN UPPER PAYMENT LIMIT FOR A20PRESCRIPTION DRUG PRODUCT THAT IS ON THE FEDERAL FOOD AND DRUG21ADMINISTRATION PRESCRIPTION DRUG SHORTAGE LIST; AND

- 22
- (2) **REQUIRE THE BOARD TO:**

23(I)MONITOR THE AVAILABILITY OF ANY PRESCRIPTION DRUG24PRODUCT FOR WHICH IT SETS AN UPPER PAYMENT LIMIT; AND

(II) IF THERE BECOMES A SHORTAGE OF THE PRESCRIPTION
DRUG PRODUCT IN THE STATE, RECONSIDER OR SUSPEND THE UPPER PAYMENT
LIMIT.

(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 ASSEMBLY, IN ACCORDANCE WITH § 2–1257
OF THE STATE GOVERNMENT ARTICLE, FOR ITS APPROVAL.

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THE LEGISLATIVE POLICY COMMITTEE SHALL HAVE 45 DAYS TO 1 (2) $\mathbf{2}$ APPROVE THE PLAN OF ACTION. IF THE LEGISLATIVE POLICY COMMITTEE DOES NOT APPROVE 3 (3) THE PLAN OF ACTION, THE BOARD SHALL SUBMIT THE PLAN TO THE GOVERNOR AND 4 THE ATTORNEY GENERAL FOR APPROVAL. $\mathbf{5}$ 6 (4) THE GOVERNOR AND THE ATTORNEY GENERAL SHALL HAVE 45 DAYS TO APPROVE THE PLAN OF ACTION. 7

8 (5) THE BOARD MAY NOT SET UPPER PAYMENT LIMITS UNLESS THE 9 PLAN IS APPROVED, IN ACCORDANCE WITH THIS SUBSECTION, BY:

- 10 (I) THE LEGISLATIVE POLICY COMMITTEE; OR
- 11 (II) 1. THE GOVERNOR; AND
- 12 **2. THE ATTORNEY GENERAL.**
- 13 **21–2C–14.**

14 (A) IF A PLAN OF ACTION IS APPROVED UNDER § 21–2C–13(D) OF THIS 15 SUBTITLE, THE BOARD MAY SET UPPER PAYMENT LIMITS FOR PRESCRIPTION DRUG 16 PRODUCTS THAT ARE:

17 (1) PURCHASED OR PAID FOR BY A UNIT OF STATE OR LOCAL 18 GOVERNMENT OR AN ORGANIZATION ON BEHALF OF A UNIT OF STATE OR LOCAL 19 GOVERNMENT, INCLUDING:

- 20 (I) STATE OR COUNTY CORRECTIONAL FACILITIES;
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(II) STATE HOSPITALS; AND

22 (III) HEALTH CLINICS AT STATE INSTITUTIONS OF HIGHER 23 EDUCATION;

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

27 (3) PURCHASED FOR OR PAID FOR BY THE MARYLAND STATE 28 MEDICAL ASSISTANCE PROGRAM. 1 (B) THE UPPER PAYMENT LIMITS SET UNDER SUBSECTION (A) OF THIS 2 SECTION SHALL:

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

5 (2) BE SET IN ACCORDANCE WITH THE CRITERIA ESTABLISHED IN 6 REGULATIONS ADOPTED BY THE BOARD.

7 (C) (1) THE BOARD SHALL:

8 (I) MONITOR THE AVAILABILITY OF ANY PRESCRIPTION DRUG 9 PRODUCT FOR WHICH IT SETS AN UPPER PAYMENT LIMIT; AND

10 (II) IF THERE BECOMES A SHORTAGE OF THE PRESCRIPTION 11 DRUG PRODUCT IN THE STATE, RECONSIDER WHETHER THE UPPER PAYMENT LIMIT 12 SHOULD BE SUSPENDED OR ALTERED.

13 (2) AN UPPER PAYMENT LIMIT SET UNDER SUBSECTION (A) OF THIS 14 SECTION MAY NOT BE APPLIED TO A PRESCRIPTION DRUG PRODUCT WHILE THE 15 PRESCRIPTION DRUG PRODUCT IS ON THE FEDERAL FOOD AND DRUG 16 ADMINISTRATION PRESCRIPTION DRUG SHORTAGE LIST.

17 **21–2C–15.**

18 (A) A PERSON AGGRIEVED BY AN UPPER PAYMENT LIMIT SET BY THE 19 BOARD MAY REQUEST AN APPEAL WITHIN 30 DAYS AFTER THE BOARD MAKES THE 20 DECISION TO SET THE LIMIT.

21(B)THE BOARD SHALL HEAR THE APPEAL AND MAKE A FINAL DECISION22WITHIN 60 DAYS AFTER THE APPEAL IS REQUESTED.

(C) ANY PERSON AGGRIEVED BY A FINAL DECISION OF THE BOARD ISSUED
UNDER SUBSECTION (B) OF THIS SECTION MAY PETITION FOR JUDICIAL REVIEW AS
PROVIDED BY THE ADMINISTRATIVE PROCEDURE ACT.

26 **21–2C–16.**

ON OR BEFORE DECEMBER 1, 2026, THE BOARD, IN CONSULTATION WITH THE STAKEHOLDER COUNCIL, SHALL REPORT TO THE SENATE FINANCE COMMITTEE AND THE HOUSE HEALTH AND GOVERNMENT OPERATIONS COMMITTEE, IN ACCORDANCE WITH § 2–1257 OF THE STATE GOVERNMENT ARTICLE, ON:

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1 (1) THE LEGALITY, OBSTACLES, AND BENEFITS OF SETTING UPPER 2 PAYMENT LIMITS ON ALL PURCHASES AND PAYOR REIMBURSEMENTS OF 3 PRESCRIPTION DRUG PRODUCTS IN THE STATE; AND

4 (2) RECOMMENDATIONS REGARDING WHETHER THE GENERAL 5 ASSEMBLY SHOULD PASS LEGISLATION TO EXPAND THE AUTHORITY OF THE BOARD 6 TO SET UPPER PAYMENT LIMITS TO ALL PURCHASES AND PAYOR REIMBURSEMENTS 7 OF PRESCRIPTION DRUG PRODUCTS IN THE STATE.

8 SECTION 2. AND BE IT FURTHER ENACTED, That this Act is an emergency 9 measure, is necessary for the immediate preservation of the public health or safety, has 10 been passed by a yea and nay vote supported by three—fifths of all the members elected to 11 each of the two Houses of the General Assembly, and shall take effect from the date it is 12 enacted.

Approved:

Governor.

President of the Senate.

Speaker of the House of Delegates.