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By: Delegate Pendergrass

Introduced and read first time: February 6, 2020 Assigned to: Health and Government Operations

A BILL ENTITLED

1 AN ACT concerning

Prescription Drug Affordability Board – Meetings, Legal Advisor, and Technical Changes

4 FOR the purpose of altering the frequency at which the Prescription Drug Affordability $\mathbf{5}$ Board is required to meet; repealing the requirement that the Board hire general 6 counsel; providing that the Attorney General is the legal advisor for the Board; 7 requiring the Attorney General to designate a certain attorney as counsel to the 8 Board; authorizing the Attorney General to assign certain attorneys to the Board 9 under certain circumstances; establishing certain duties for the counsel to the Board; requiring the counsel of the Board to perform certain duties under certain control 1011 and supervision; prohibiting the Attorney General from reassigning the counsel to 12the Board except under certain circumstances; clarifying that on or after a certain 13 date the Board may set certain upper payment limits in accordance with a certain 14 plan of action; repealing a certain termination provision; and generally relating to the Prescription Drug Affordability Board. 15

- 16 BY repealing and reenacting, with amendments,
- 17 Article Health General
- 18 Section 21–2C–03(c)(1) and (e)(1)(i)
- 19 Annotated Code of Maryland
- 20 (2019 Replacement Volume)
- 21 BY adding to
- 22 Article Health General
- 23 Section 21–2C–03(i)
- 24 Annotated Code of Maryland
- 25 (2019 Replacement Volume)
- 26 BY repealing and reenacting, without amendments,
- 27 Article Health General
- 28 Section 21–2C–13

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



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	Z HOUSE BILL 1100
$\frac{1}{2}$	Annotated Code of Maryland (2019 Replacement Volume)
$egin{array}{c} 3 \ 4 \ 5 \end{array}$	BY repealing and reenacting, with amendments, Chapter 692 of the Acts of the General Assembly of 2019 Section 9
	BY repealing and reenacting, with amendments, Article – Health – General Section 21–2C–13 through 21–2C–15 Annotated Code of Maryland (2019 Replacement Volume) (As enacted by Chapter 692 of the Acts of the General Assembly of 2019)
12 13	SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:
14	Article – Health – General
15	21–2C–03.
$\begin{array}{c} 16 \\ 17 \end{array}$	(c) (1) The chair shall hire an executive director [, general counsel,] and staff for the Board.
18 19	(e) (1) (i) Subject to subparagraphs (ii) and (iv) of this paragraph, the Board shall meet in open session at least [once every 6 weeks] FOUR TIMES A YEAR.
20	(I) (1) THE ATTORNEY GENERAL IS THE LEGAL ADVISER TO THE BOARD.
$\begin{array}{c} 21 \\ 22 \end{array}$	(2) THE ATTORNEY GENERAL SHALL DESIGNATE AN ASSISTANT ATTORNEY GENERAL AS COUNSEL TO THE BOARD.
$\begin{array}{c} 23\\ 24\\ 25 \end{array}$	(3) AS NEEDED, THE ATTORNEY GENERAL MAY ASSIGN ADDITIONAL ASSISTANT ATTORNEYS GENERAL TO THE BOARD TO GIVE EFFECTIVE LEGAL ADVICE AND COUNSEL.
$\frac{26}{27}$	(4) THE COUNSEL TO THE BOARD MAY NOT HAVE A DUTY OTHER THAN TO:
$\begin{array}{c} 28\\ 29 \end{array}$	(I) GIVE THE LEGAL AID, ADVICE, AND COUNSEL REQUIRED BY THE BOARD;
30 31	(II) SUPERVISE THE OTHER ASSISTANT ATTORNEYS GENERAL ASSIGNED TO THE BOARD, IF ANY; AND

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1 (III) PERFORM FOR THE DEPARTMENT THE DUTIES THAT THE 2 ATTORNEY GENERAL ASSIGNS.

3 (5) THE COUNSEL SHALL PERFORM THESE DUTIES SUBJECT TO THE
 4 CONTROL AND SUPERVISION OF THE ATTORNEY GENERAL.

5 (6) AFTER THE ATTORNEY GENERAL DESIGNATES THE COUNSEL TO 6 THE BOARD, THE ATTORNEY GENERAL MAY NOT REASSIGN THE COUNSEL WITHOUT 7 CONSULTING THE BOARD.

8 21–2C–13.

9 (a) If, under § 21–2C–07 of this subtitle, the Board finds that it is in the best 10 interest of the State to establish a process for setting upper payment limits for prescription 11 drug products that it determines have led or will lead to an affordability challenge, the 12 Board, in conjunction with the Stakeholder Council, shall draft a plan of action for 13 implementing the process that includes the criteria the Board shall use to set upper 14 payment limits.

- 15 (b) The criteria for setting upper payment limits shall include consideration of:
- 16 (1) The cost of administering the prescription drug product;
- 17 (2) The cost of delivering the prescription drug product to consumers; and
- 18 (3) Other relevant administrative costs related to the prescription drug19 product.
- 20 (c) The process for setting upper payment limits shall:

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

- 24 (2) Require the Board to:
- (i) Monitor the availability of any prescription drug product forwhich it sets an upper payment limit; and

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

(d) (1) If a plan of action is drafted under subsection (a) of this section, on or
before July 1, 2021, 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.

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

3 (3) If the Legislative Policy Committee does not approve the plan of action, 4 the Board shall submit the plan to the Governor and the Attorney General for approval.

5 (4) The Governor and the Attorney General shall have 45 days to approve 6 the plan of action.

- 7 (5) The Board may not set upper payment limits unless the plan is 8 approved, in accordance with this subsection, by:
- 9 (i) The Legislative Policy Committee; or

10 (ii) 1. The Governor; and

11 2. The Attorney General.

Chapter 692 of the Acts of 2019

13 SECTION 9. AND BE IT FURTHER ENACTED, That Section 3 of this Act shall take effect contingent on receipt by the Prescription Drug Affordability Board established under 14 15 21–2C–02 of the Health – General Article, as enacted by Section 1 of this Act of approval 16by the Legislative Policy Committee of the General Assembly or the Governor and the 17Attorney General of the plan of action for implementing a process for setting upper payment 18 limits in accordance with § 21–2C–13 of the Health – General Article, as enacted by Section 19 2 of this Act. The Board, within 5 days after receiving approval from the Legislative Policy 20Committee or the Governor and the Attorney General, shall forward evidence of the 21approval to the Department of Legislative Services, 90 State Circle, Annapolis, Maryland 2221401. If the Board receives approval for the plan of action on or before January 1, 2023, 23Section 2 of this Act, with no further action required by the General Assembly, shall be 24abrogated and of no further force and effect and Section 3 of this Act shall take effect on 25the date evidence of the approval is received by the Department of Legislative Services in 26accordance with this section. If the Board does not receive approval of the plan of action on 27or before January 1, 2023, Section 2 of this Act, with no further action required by the 28General Assembly, shall be abrogated and of no further force and effect and Section 3 of 29this Act shall be null and void.

- 30 SECTION 2. AND BE IT FURTHER ENACTED, That the Laws of Maryland read
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Article – Health – General

33 [21–2C–13.] **21–2C–14.**

as follows:

34 (a) On or after January 1, 2022, the Board, IN ACCORDANCE WITH THE PLAN

$\frac{1}{2}$	OF ACTION APPROVED UNDER § 21–2C–13 OF THIS SUBTITLE, may set upper payment limits for prescription drug products that are:
$\frac{3}{4}$	(1) Purchased or paid for by a unit of State or local government or an organization on behalf of a unit of State or local government, including:
5	(i) State or county correctional facilities;
6	(ii) State hospitals; and
7	(iii) Health clinics at State institutions of higher education;
8 9 10	(2) Paid for through a health benefit plan on behalf of a unit of State or local government, including a county, bicounty, or municipal employee health benefit plan; or
$\begin{array}{c} 11 \\ 12 \end{array}$	(3) Purchased for or paid for by the Maryland State Medical Assistance Program.
13	(b) The upper payment limits set under subsection (a) of this section shall:
$\begin{array}{c} 14 \\ 15 \end{array}$	(1) Be for prescription drug products that have led or will lead to an affordability challenge; and
$\begin{array}{c} 16 \\ 17 \end{array}$	(2) Be set in accordance with the criteria established in regulations adopted by the Board.
18	(c) (1) The Board shall:
19 20	(i) Monitor the availability of any prescription drug product for which it sets an upper payment limit; and
$\begin{array}{c} 21 \\ 22 \end{array}$	(ii) If there becomes a shortage of the prescription drug product in the State, reconsider whether the upper payment limit should be suspended or altered.
$23 \\ 24 \\ 25$	(2) An upper payment limit set under subsection (a) of this section may not be applied to a prescription drug product while the prescription drug product is on the federal Food and Drug Administration prescription drug shortage list.
26	[21–2C–14.] 21–2C–15.
$\begin{array}{c} 27\\ 28 \end{array}$	(a) A person aggrieved by a decision of the Board may request an appeal of the decision within 30 days after the finding of the Board.
29 30	(b) The Board shall hear the appeal and make a final decision within 60 days after the appeal is requested.

1 (c) Any person aggrieved by a final decision of the Board may petition for judicial 2 review as provided by the Administrative Procedure Act.

3 [21–2C–15.] **21–2C–16.**

On or before December 1, 2023, 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:

8 (1) The legality, obstacles, and benefits of setting upper payment limits on 9 all purchases and payor reimbursements of prescription drug products in the State; and

10 (2) Recommendations regarding whether the General Assembly should 11 pass legislation to expand the authority of the Board to set upper payment limits to all 12 purchases and payor reimbursements of prescription drug products in the State.

13 SECTION 3. AND BE IT FURTHER ENACTED, That this Act shall take effect June14 1, 2020.

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