

HOUSE BILL 1100

J1, C3

0lr2869

By: ~~Delegate Pendergrass~~ Delegates Pendergrass, Bagnall, Barron, Belcastro, Bhandari, Carr, Charles, Chisholm, Cullison, Hill, Johnson, Kelly, Kerr, Kipke, Krebs, R. Lewis, Morgan, Pena-Melnyk, Reilly, Rosenberg, Saab, Sample-Hughes, Szeliga, and K. Young

Introduced and read first time: February 6, 2020

Assigned to: Health and Government Operations

Committee Report: Favorable with amendments

House action: Adopted

Read second time: March 9, 2020

CHAPTER _____

1 AN ACT concerning

2 **Prescription Drug Affordability Board – Meetings, Legal Advisor, Reports, and**
3 **Technical Changes**

4 FOR the purpose of altering the frequency at which the Prescription Drug Affordability
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;
10 requiring the counsel of the Board to perform certain duties under certain control
11 and supervision; prohibiting the Attorney General from reassigning the counsel to
12 the Board except under certain circumstances; altering certain dates for certain
13 reporting requirements; clarifying that on or after a certain date the Board may set
14 certain upper payment limits in accordance with a certain plan of action; repealing
15 a certain termination provision; and generally relating to the Prescription Drug
16 Affordability Board.

17 BY repealing and reenacting, with amendments,
18 Article – Health – General
19 Section 21–2C–03(c)(1) and (e)(1)(i), 21–2C–07, and 21–2C–08(a)
20 Annotated Code of Maryland
21 (2019 Replacement Volume)

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.

Underlining indicates amendments to bill.

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



1 BY adding to
 2 Article – Health – General
 3 Section 21–2C–03(i)
 4 Annotated Code of Maryland
 5 (2019 Replacement Volume)

6 BY repealing and reenacting, without amendments,
 7 Article – Health – General
 8 Section 21–2C–13
 9 Annotated Code of Maryland
 10 (2019 Replacement Volume)

11 BY repealing and reenacting, with amendments,
 12 Chapter 692 of the Acts of the General Assembly of 2019
 13 Section 5, 7, and 9

14 BY repealing and reenacting, with amendments,
 15 Article – Health – General
 16 Section 21–2C–13 through 21–2C–15
 17 Annotated Code of Maryland
 18 (2019 Replacement Volume)
 19 (As enacted by Chapter 692 of the Acts of the General Assembly of 2019)

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

22 **Article – Health – General**

23 21–2C–03.

24 (c) (1) The chair shall hire an executive director[, general counsel,] and staff
 25 for the Board.

26 (e) (1) (i) Subject to subparagraphs (ii) and (iv) of this paragraph, the
 27 Board shall meet in open session at least [once every 6 weeks] **FOUR TIMES A YEAR.**

28 **(1) (1) THE ATTORNEY GENERAL IS THE LEGAL ADVISER TO THE BOARD.**

29 **(2) THE ATTORNEY GENERAL SHALL DESIGNATE AN ASSISTANT**
 30 **ATTORNEY GENERAL AS COUNSEL TO THE BOARD.**

31 **(3) AS NEEDED, THE ATTORNEY GENERAL MAY ASSIGN ADDITIONAL**
 32 **ASSISTANT ATTORNEYS GENERAL TO THE BOARD TO GIVE EFFECTIVE LEGAL**
 33 **ADVICE AND COUNSEL.**

1 **(4) THE COUNSEL TO THE BOARD MAY NOT HAVE A DUTY OTHER**
2 **THAN TO:**

3 **(I) GIVE THE LEGAL AID, ADVICE, AND COUNSEL REQUIRED BY**
4 **THE BOARD;**

5 **(II) SUPERVISE THE OTHER ASSISTANT ATTORNEYS GENERAL**
6 **ASSIGNED TO THE BOARD, IF ANY; AND**

7 **(III) PERFORM FOR THE ~~DEPARTMENT~~ BOARD THE DUTIES**
8 **THAT THE ATTORNEY GENERAL ASSIGNS.**

9 **(5) THE COUNSEL SHALL PERFORM THESE DUTIES SUBJECT TO THE**
10 **CONTROL AND SUPERVISION OF THE ATTORNEY GENERAL.**

11 **(6) AFTER THE ATTORNEY GENERAL DESIGNATES THE COUNSEL TO**
12 **THE BOARD, THE ATTORNEY GENERAL MAY NOT REASSIGN THE COUNSEL WITHOUT**
13 **CONSULTING THE BOARD.**

14 21-2C-07.

15 On or before December 31, [2020] 2021, the Board, in consultation with the
16 Stakeholder Council, shall:

17 (1) Study:

18 (i) The entire pharmaceutical distribution and payment system in
19 the State; and

20 (ii) Policy options being used in other states and countries to lower
21 the list price of pharmaceuticals, including:

22 1. Setting upper payment limits;

23 2. Using a reverse auction marketplace; and

24 3. Implementing a bulk purchasing process; and

25 (2) Report its findings and recommendations, including findings for each
26 option studied under item (1)(ii) of this section and any legislation required to implement
27 the recommendations, to the Senate Finance Committee and the House Health and
28 Government Operations Committee in accordance with § 2-1257 of the State Government
29 Article.

30 21-2C-08.

1 (a) On or before December 31, [2020] 2021, the Board shall:

2 (1) Collect and review publicly available information regarding
3 prescription drug product manufacturers, health insurance carriers, health maintenance
4 organizations, managed care organizations, wholesale distributors, and pharmacy benefits
5 managers; and

6 (2) (i) Identify states that require reporting on the cost of prescription
7 drug products; and

8 (ii) Initiate a process of entering into memoranda of understanding
9 with the states identified under item (i) of this item to aid in the collection of transparency
10 data for prescription drug products.

11 21-2C-13.

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

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

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

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

21 (3) Other relevant administrative costs related to the prescription drug
22 product.

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

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

27 (2) Require the Board to:

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

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

1 (d) (1) If a plan of action is drafted under subsection (a) of this section, on or
2 before July 1, 2021, the Board shall submit the plan of action to the Legislative Policy
3 Committee of the General Assembly, in accordance with § 2–1257 of the State Government
4 Article, for its approval.

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

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

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

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

13 (i) The Legislative Policy Committee; or

14 (ii) 1. The Governor; and

15 2. The Attorney General.

16 Chapter 692 of the Acts of 2019

17 SECTION 5. AND BE IT FURTHER ENACTED, That, on or before June 1, [2020]
18 2022, the Prescription Drug Affordability Board shall:

19 (1) conduct a study of the operation of the generic drug market in the
20 United States that includes a review of physician–administered drugs and considers:

21 (i) the prices of generic drugs on a year–over–year basis;

22 (ii) the degree to which generic drug prices affect yearly insurance
23 premium changes;

24 (iii) annual changes in insurance cost–sharing for generic drugs;

25 (iv) the potential for and history of drug shortages;

26 (v) the degree to which generic drug prices affect yearly State
27 Medicaid spending; and

28 (vi) any other relevant study questions; and

29 (2) report its findings to the General Assembly, in accordance with §
30 2–1246 of the State Government Article.

1 (ii) State hospitals; and

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

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

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

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

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

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

13 (c) (1) The Board shall:

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

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

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

21 **[21-2C-14.] 21-2C-15.**

22 (a) A person aggrieved by a decision of the Board may request an appeal of the
23 decision within 30 days after the finding of the Board.

24 (b) The Board shall hear the appeal and make a final decision within 60 days
25 after the appeal is requested.

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

28 **[21-2C-15.] 21-2C-16.**

29 On or before December 1, 2023, the Board, in consultation with the Stakeholder
30 Council, shall report to the Senate Finance Committee and the House Health and

1 Government Operations Committee, in accordance with § 2–1257 of the State Government
2 Article, on:

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

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

8 SECTION 3. AND BE IT FURTHER ENACTED, That this Act shall take effect June
9 1, 2020.

Approved:

Governor.

Speaker of the House of Delegates.

President of the Senate.