

Chapter 425

**(House Bill 1100)**

AN ACT concerning

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

FOR the purpose of altering the frequency at which the Prescription Drug Affordability Board is required to meet; repealing the requirement that the Board hire general counsel; providing that the Attorney General is the legal advisor for the Board; requiring the Attorney General to designate a certain attorney as counsel to the Board; authorizing the Attorney General to assign certain attorneys to the Board 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 and supervision; prohibiting the Attorney General from reassigning the counsel to the Board except under certain circumstances; altering certain dates for certain reporting requirements; clarifying that on or after a certain date the Board may set certain upper payment limits in accordance with a certain plan of action; repealing a certain termination provision; and generally relating to the Prescription Drug Affordability Board.

BY repealing and reenacting, with amendments,

Article – Health – General

Section 21–2C–03(c)(1) and (e)(1)(i), 21–2C–07, and 21–2C–08(a)

Annotated Code of Maryland

(2019 Replacement Volume)

BY adding to

Article – Health – General

Section 21–2C–03(i)

Annotated Code of Maryland

(2019 Replacement Volume)

BY repealing and reenacting, without amendments,

Article – Health – General

Section 21–2C–13

Annotated Code of Maryland

(2019 Replacement Volume)

BY repealing and reenacting, with amendments,

Chapter 692 of the Acts of the General Assembly of 2019

Section 5, 7, and 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)

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

**Article – Health – General**

21–2C–03.

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

(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.**

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

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

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

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

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

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

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

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

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

21-2C-07.

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

(1) Study:

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

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

1. Setting upper payment limits;

2. Using a reverse auction marketplace; and

3. Implementing a bulk purchasing process; and

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

21-2C-08.

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

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

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

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

21-2C-13.

(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.

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

- (1) The cost of administering the prescription drug product;
- (2) The cost of delivering the prescription drug product to consumers; and
- (3) Other relevant administrative costs related to the prescription drug product.

(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

(2) Require the Board to:

(i) Monitor the availability of any prescription drug product 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, 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.

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

(3) 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.

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

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

- (i) The Legislative Policy Committee; or
- (ii) 1. The Governor; and
  - 2. The Attorney General.

### Chapter 692 of the Acts of 2019

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

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

- (i) the prices of generic drugs on a year-over-year basis;
- (ii) the degree to which generic drug prices affect yearly insurance premium changes;
- (iii) annual changes in insurance cost-sharing for generic drugs;
- (iv) the potential for and history of drug shortages;
- (v) the degree to which generic drug prices affect yearly State Medicaid spending; and
- (vi) any other relevant study questions; and

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

SECTION 7. AND BE IT FURTHER ENACTED, That, on or before December 1, [2020] 2021, the State Designated Health Information Exchange and the Prescription Drug Affordability Board established under § 21-2C-02 of the Health – General Article, as enacted by Section 1 of this Act, jointly shall:

(1) study how the Information Exchange can provide de-identified provider and patient data to the Board; and

(2) report their findings and recommendations, including any necessary statutory changes, to the General Assembly, in accordance with § 2-1246 of the State Government Article.

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 § 21–2C–02 of the Health – General Article, as enacted by Section 1 of this Act of approval by the Legislative Policy Committee of the General Assembly or the Governor and the Attorney General of the plan of action for implementing a process for setting upper payment limits in accordance with § 21–2C–13 of the Health – General Article, as enacted by Section 2 of this Act. The Board, within 5 days after receiving approval from the Legislative Policy Committee or the Governor and the Attorney General, shall forward evidence of the approval to the Department of Legislative Services, 90 State Circle, Annapolis, Maryland 21401. If the Board receives approval for the plan of action on or before January 1, 2023, [Section 2 of this Act, with no further action required by the General Assembly, shall be abrogated and of no further force and effect and] Section 3 of this Act shall take effect on the date evidence of the approval is received by the Department of Legislative Services in accordance with this section. If the Board does not receive approval of the plan of action on or before January 1, 2023, Section 2 of this Act, with no further action required by the General Assembly, shall be abrogated and of no further force and effect and Section 3 of this Act shall be null and void.

SECTION 2. AND BE IT FURTHER ENACTED, That the Laws of Maryland read as follows:

### Article – Health – General

#### [21–2C–13.] 21–2C–14.

(a) On or after January 1, 2022, the Board, **IN ACCORDANCE WITH THE PLAN OF ACTION APPROVED UNDER § 21–2C–13 OF THIS SUBTITLE**, may set upper payment limits for prescription drug products that are:

(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:

- (i) State or county correctional facilities;
- (ii) State hospitals; and
- (iii) Health clinics at State institutions of higher education;

(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

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

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

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

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

(c) (1) The Board shall:

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

(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.

(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.

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

(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.

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

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

**[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:

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

(2) Recommendations regarding whether the General Assembly should pass 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.

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

**Enacted under Article II, § 17(c) of the Maryland Constitution, May 8, 2020.**