HOUSE BILL 162

J3, C3 1lr1100

(PRE–FILED)

By: **Delegate Ivey**
Requested: October 25, 2020
Introduced and read first time: January 13, 2021
Assigned to: Health and Government Operations

A BILL ENTITLED

AN ACT concerning

Prescription Drug Affordability Board – Upper Payment Limits and Reports

FOR the purpose of altering a certain requirement that the Prescription Drug Affordability Board, in conjunction with a certain council, draft a certain plan for setting upper payment limits for prescription drug products; altering the date by which the Board is required to submit the plan to a certain committee of the General Assembly; requiring, rather than authorizing, the Board to set upper payment limits for certain prescription drug products and altering the date on or after which the limits are to be set; repealing a certain requirement that the Board, in consultation with a certain council, submit a certain report to certain committees of the General Assembly on or before a certain date; altering the dates by which the Board is required to study certain matters, perform certain actions, and report certain findings and recommendations to certain committees of the General Assembly; altering a certain termination provision; and generally relating to the Prescription Drug Affordability Board.

BY repealing and reenacting, without amendments,
Article – Health – General
Section 21–2C–01
Annotated Code of Maryland
(2019 Replacement Volume and 2020 Supplement)

BY repealing and reenacting, with amendments,
Article – Health – General
Section 21–2C–07, 21–2C–08(a), 21–2C–13, and 21–2C–14
Annotated Code of Maryland
(2019 Replacement Volume and 2020 Supplement)

BY repealing
Article – Health – General

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

Section 21–2C–16
Annotated Code of Maryland
(2019 Replacement Volume and 2020 Supplement)

BY repealing and reenacting, with amendments,
Chapter 692 of the Acts of the General Assembly of 2019, as amended by Chapter 425 of the Acts of the General Assembly of 2020
Section 9

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

Article – Health – General

21–2C–01.

(a) In this subtitle the following words have the meanings indicated.

(b) "Biologic" means a drug that is produced or distributed in accordance with a biologics license application approved under 42 C.F.R. § 447.502.

(c) "Biosimilar" means a drug that is produced or distributed in accordance with a biologics license application approved under 42 U.S.C. § 262(k)(3).

(d) "Board" means the Prescription Drug Affordability Board.

(e) (1) "Brand name drug" means a drug that is produced or distributed in accordance with an original new drug application approved under 21 U.S.C. § 355(c).

(2) "Brand name drug" does not include an authorized generic as defined by 42 C.F.R. § 447.502.

(f) "Generic drug" means:

(1) A retail drug that is marketed or distributed in accordance with an abbreviated new drug application, approved under 21 U.S.C. § 355(j);

(2) An authorized generic as defined by 42 C.F.R. § 447.502; or

(3) A drug that entered the market before 1962 that was not originally marketed under a new drug application.

(g) "Manufacturer" means an entity that:

(1) (i) Engages in the manufacture of a prescription drug product; or

(ii) Enters into a lease with another manufacturer to market and distribute a prescription drug product under the entity's own name; and

(2) Sets or changes the wholesale acquisition cost of the prescription drug product it manufactures or markets.

(h) "Prescription drug product" means a brand name drug, a generic drug, a biologic, or a biosimilar.

(i) "Stakeholder Council" means the Prescription Drug Affordability Stakeholder Council.

21–2C–07.

On or before **[**December 31, 2021**]** **OCTOBER 1, 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, 2021**]** **OCTOBER 1, 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**]** **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**]** **ON** or before **[**July**]** **OCTOBER** 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.

21–2C–14.

(a) On or after **[**January 1, 2022**]** **FEBRUARY 1, 2022**, the Board, in accordance with the plan of action approved under § 21–2C–13 of this subtitle **AND SUBJECT TO SUBSECTION (C) OF THIS SECTION**, **[**may**]** **SHALL** 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–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.**]**

Chapter 692 of the Acts of 2019, as amended by Chapter 425 of the Acts of 2020

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**]** **FEBRUARY 1, 2022**, 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**]** **FEBRUARY 1, 2022**, 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 this Act shall take effect June 1, 2021.