Chapter 611

(House Bill 424)

AN ACT concerning

Prescription Drug Affordability Board – Authority ~~for Upper Payment Limits~~ *and Stakeholder Council Membership*
(Lowering Prescription Drug Costs for All Marylanders Now Act)

FOR the purpose of *altering the membership of the Prescription Drug Affordability Stakeholder Council;* requiring the Prescription Drug Affordability Board, under certain circumstances, to establish a process for setting upper payment limits for ~~all~~ purchases and payor reimbursements of prescription drug products in the State that the Board determines have led or will lead to affordability challenges; authorizing the Board to reconsider an upper payment limit for a drug that becomes a current shortage; altering requirements related to the setting of upper payment limits by the Board; requiring the Board to confer with the Maryland Medical Assistance Program before establishing an upper payment limit that applies to the Program; prohibiting the Board from taking certain actions related to upper payment limits; and generally relating to the Prescription Drug Affordability Board.

BY repealing and reenacting, with amendments,
Article – Health – General
Section 21–2C–01, *21–2C–04,* 21–2C–13, and 21–2C–14
Annotated Code of Maryland
(2023 Replacement Volume and 2024 Supplement)

BY repealing and reenacting, without amendments,
Article – Health – General
Section *21–2C–09(c) and* 21–2C–11(a)
Annotated Code of Maryland
(2023 Replacement Volume and 2024 Supplement)

BY adding to
Article – Health – General
Section 21–2C–09(d) and (e) and 21–2C–16
Annotated Code of Maryland
(2023 Replacement Volume and 2024 Supplement)

BY repealing
Article – Health – General
Section 21–2C–11(d) and 21–2C–16
Annotated Code of Maryland
(2023 Replacement Volume and 2024 Supplement)

~~BY adding to~~

~~Article – Health – General~~
~~Section 21–2C–16~~
~~Annotated Code of Maryland~~
~~(2023 Replacement Volume and 2024 Supplement)~~

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) "CURRENT SHORTAGE" MEANS A DRUG:

(1) LISTED AS CURRENT ON THE FEDERAL FOOD AND DRUG ADMINISTRATION'S DRUG SHORTAGE DATABASE; OR

(2) OTHERWISE DETERMINED BY THE BOARD TO BE IN SHORT SUPPLY IN THE STATE.

[(f)**] (G)** "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)**] (H)** "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)**] (I)** "Prescription drug product" means a brand name drug, a generic drug, a biologic, or a biosimilar.

[(i)**] (J)** "Stakeholder Council" means the Prescription Drug Affordability Stakeholder Council.

21–2C–04.

(a) There is a Prescription Drug Affordability Stakeholder Council.

(b) The purpose of the Stakeholder Council is to provide stakeholder input to assist the Board in making decisions as required under this subtitle.

*(c) (1) The Stakeholder Council consists of **[**26**]** members appointed in accordance with this subsection.*

(2) The Speaker of the House of Delegates shall appoint:

(i) One representative of generic drug corporations;

(ii) One representative of nonprofit insurance carriers;

(iii) One representative of a statewide health care advocacy coalition;

(iv) One representative of a statewide advocacy organization for seniors;

(v) One representative of a statewide organization for diverse communities;

(vi) One representative of a labor union;

*(vii) **ONE REPRESENTATIVE OF THE RARE DISEASE COMMUNITY;***

***(VIII)** One health services researcher specializing in prescription drugs; and*

[(viii)**]** **(IX)** One public member at the discretion of the Speaker of the House of Delegates.

(3) The President of the Senate shall appoint:

(i) One representative of brand name drug corporations;

(ii) One representative of physicians;

(iii) One representative of nurses;

(iv) One representative of hospitals;

(v) One representative of dentists;

(vi) **ONE REPRESENTATIVE OF ONCOLOGISTS;**

(VII) One representative of managed care organizations;

[(vii)**]** **(VIII)** One representative of the Department of Budget and Management;

[(viii)**]** **(IX)** One clinical researcher; and

[(ix)**]** **(X)** One public member at the discretion of the President of the Senate.

(4) The Governor shall appoint:

(i) One representative of brand name drug corporations;

(ii) One representative of generic drug corporations;

(iii) One representative of biotechnology companies;

(iv) One representative of for–profit health insurance carriers;

(v) One representative of employers;

(vi) One representative of pharmacy benefits managers;

(vii) One representative of pharmacists;

(viii) One pharmacologist; **[**and**]**

(ix) ***ONE REPRESENTATIVE OF A PATIENT ADVOCACY ORGANIZATION; AND***

(X) *One public member at the discretion of the Governor.*

(5) Collectively, the members of the Stakeholder Council shall have knowledge of the following:

(i) The pharmaceutical business model;

(ii) Supply chain business models;

(iii) The practice of medicine or clinical training;

(iv) Consumer or patient perspectives;

(v) Health care costs trends and drivers;

(vi) Clinical and health services research; or

(vii) The State's health care marketplace.

(6) To the extent practicable and consistent with federal and State law, the membership of the Stakeholder Council shall reflect the racial, ethnic, and gender diversity of the State.

(7) From among the membership of the Stakeholder Council, the Board chair shall appoint two members to be cochairs of the Stakeholder Council.

(d) (1) The term of a member is 3 years.

(2) The initial members of the Stakeholder Council shall serve staggered terms as required by the terms provided for members on October 1, 2019.

(e) A member of the Stakeholder Council:

(1) May not receive compensation as a member of the Stakeholder Council; but

(2) Is entitled to reimbursement for expenses under the Standard State Travel Regulations, as provided in the State budget.

21–2C–09.

(c) On or before December 31, 2020, and each December 31 thereafter, the Board shall submit to the Senate Finance Committee and the House Health and Government Operations Committee, in accordance with § 2–1257 of the State Government Article, a report that includes:

(1) Price trends for prescription drug products;

(2) The number of prescription drug products that were subject to Board review and the results of the review; and

(3) Any recommendations the Board may have on further legislation needed to make prescription drug products more affordable in the State.

(D) IF THE BOARD SETS A NEW UPPER PAYMENT LIMIT, TO THE EXTENT PRACTICABLE, THE BOARD SHALL INCLUDE IN THE FIRST REPORT THAT IS REQUIRED UNDER SUBSECTION (C) OF THIS SECTION AFTER THE UPPER PAYMENT LIMIT HAS BEEN IN EFFECT FOR 1 YEAR INFORMATION ON THE EFFECTS OF THE UPPER PAYMENT LIMIT, BASED ON AVAILABLE TIMELY DATA, FOR THE FOLLOWING:

(1) PATIENT OUT–OF–POCKET COSTS INCLUDING WHETHER THE UPPER PAYMENT LIMIT WAS ASSOCIATED WITH INCREASES OR DECREASES IN WHAT PATIENTS PAY FOR PRESCRIPTION DRUG PRODUCTS;

(2) PATIENT HEALTH INSURANCE PREMIUMS, INCLUDING WHETHER THE UPPER PAYMENT LIMIT IS ASSOCIATED WITH INCREASES OR DECREASES IN HEALTH INSURANCE COSTS FOR PATIENTS;

(3) PHARMACIES OPERATING IN THE STATE, INCLUDING THE IMPACT ON REIMBURSEMENT RATES AND FINANCIAL VIABILITY OF RETAIL AND INDEPENDENT PHARMACIES;

(4) PATIENT HEALTH INSURANCE FORMULARIES, INCLUDING WHETHER THE PRESCRIPTION DRUG PRODUCT SUBJECT TO THE UPPER PAYMENT LIMIT REMAINED ON FORMULARIES;

(5) PROVIDER–ADMINISTERED MEDICATIONS SUBJECT TO THE UPPER PAYMENT LIMIT, INCLUDING WHETHER PROVIDERS WERE ABLE TO ACQUIRE THE PRESCRIPTION DRUG PRODUCT SUBJECT TO THE UPPER PAYMENT LIMIT AT A RATE TO ACCOUNT FOR ACQUISITION COSTS AND WHETHER THERE WAS AN IMPACT ON PROVIDER REIMBURSEMENT;

(6) PATIENT ACCESS TO THE PRESCRIPTION DRUG PRODUCT SUBJECT TO THE UPPER PAYMENT LIMIT, WHICH MAY INCLUDE:

(I) WHETHER PRESCRIPTION DRUG PRODUCT SHORTAGES OR OTHER SUPPLY DISRUPTIONS OCCURRED AFTER THE UPPER PAYMENT LIMIT TOOK EFFECT;

(II) WHETHER FORMULARY PLACEMENT OR PLAN DESIGN CHANGES MADE THE PRESCRIPTION DRUG PRODUCT SUBJECT TO THE UPPER LIMIT MORE DIFFICULT FOR PATIENTS TO ACCESS, INCLUDING IF INSURANCE PLANS PREFERRED A PRESCRIPTION DRUG PRODUCT WITHOUT AN UPPER PAYMENT LIMIT OVER A PRESCRIPTION DRUG PRODUCT SUBJECT TO AN UPPER PAYMENT LIMIT;

(III) WHETHER THE DISTRIBUTION AND DELIVERY OF SPECIALTY OR RARE DISEASE MEDICATIONS FROM OUT–OF–STATE PHARMACIES TO PROVIDERS, PHARMACIES, OR PATIENTS WAS IMPACTED;

(IV) WHETHER PATIENTS IN COMMUNITIES OF COLOR, PATIENTS WHO ARE WOMEN, PATIENTS WITH A RARE DISEASE, OR PATIENTS IN RURAL AREAS EXPERIENCED DISPROPORTIONATE ACCESS CHALLENGES; AND

(V) WHETHER COST DIFFERENCES AS A RESULT OF THE UPPER PAYMENT LIMIT AFFECTED PATIENTS, PHARMACIES, OR PROVIDERS AND, IF THE COST DIFFERENCE RESULTED IN AN INCREASE IN COSTS, WHO WAS ULTIMATELY RESPONSIBLE FOR BEARING THE INCREASED COST;

(7) COVERED ENTITY PROVIDERS PARTICIPATING IN THE 340B DRUG DISCOUNT PROGRAM, INCLUDING THE IMPACT OF THE UPPER PAYMENT LIMIT ON THE OPERATIONS OF THE PROVIDERS AND THEIR CONTRACTED PHARMACIES; AND

(8) THE BIOTECHNOLOGY INDUSTRY IN THE STATE, INCLUDING THE IMPACT ON PHARMACEUTICAL RESEARCH AND DEVELOPMENT, INVESTMENT, AND JOB GROWTH.

(E) (1) THE BOARD MAY REQUEST INFORMATION NECESSARY TO COMPLETE THE REPORT REQUIRED UNDER SUBSECTIONS (C) AND (D) OF THIS SECTION FROM AN AFFECTED ENTITY.

(2) THE ENTITY FROM WHICH INFORMATION WAS REQUESTED UNDER PARAGRAPH (1) OF THIS SUBSECTION SHALL MAKE A GOOD FAITH EFFORT TO PROVIDE THE REQUESTED INFORMATION.

21–2C–11.

(a) In this section, "Fund" means the Prescription Drug Affordability Fund.

[(d) (1) The Board shall be established using special or general funds, which shall be repaid to the State with the funds from the Fund.

(2) If the Board receives funding from the Maryland Health Care Commission under paragraph (1) of this subsection, the Board shall repay the funds to the Commission from the Fund over a 3–year period beginning June 1, 2021.**]**

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**]** **IN ACCORDANCE WITH THE REQUIREMENTS OF THIS SECTION**.

(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) THE EFFECT THE UPPER PAYMENT LIMIT WILL HAVE ON PROVIDERS OF 340B DRUGS*;*

***(4) FOR AN UPPER PAYMENT LIMIT ON A DRUG THAT IS DESIGNATED AS A DRUG FOR A RARE DISEASE OR CONDITION, THE IMPACT OF THE UPPER PAYMENT LIMIT ON PATIENTS WITH RARE DISEASES*; AND**

[(3)**]** ~~(4)~~ ***(5)*** 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.**]**

(C) (1) IF THE BOARD PREVIOUSLY SET AN UPPER PAYMENT LIMIT FOR A DRUG THAT BECOMES A CURRENT SHORTAGE, THE BOARD MAY RECONSIDER THE PREVIOUSLY SET UPPER PAYMENT LIMIT.

(2) THE BOARD MAY NOT:

(I) ~~ESTABLISH~~ *APPLY* A NEW UPPER PAYMENT LIMIT ~~FOR~~ *TO A DRUG IN* A CURRENT SHORTAGE;

(II) ENFORCE AN UPPER PAYMENT LIMIT AGAINST PROVIDER OR PHARMACY REIMBURSEMENT REQUIREMENTS FOR MEDICARE PART C OR PART D PLANS; OR

(III) COUNT A PHARMACY DISPENSING FEE TOWARD OR SUBJECT A PHARMACY DISPENSING FEE TO AN 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.

(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) If a plan of action is approved under § 21–2C–13(d) of this subtitle**]** **IN ACCORDANCE WITH THE PLAN OF ACTION APPROVED BY THE LEGISLATIVE POLICY COMMITTEE ON OCTOBER 22, 2024**, the Board may set upper payment limits ***THROUGH REGULATIONS*** 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, 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:

(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.**]**

21–2C–16.

(A) (1) THE BOARD, IN CONSULTATION WITH THE STAKEHOLDER COUNCIL, SHALL DETERMINE WHETHER, IN ADDITION TO SETTING UPPER PAYMENT LIMITS IN ACCORDANCE WITH § 21–2C–14 OF THIS SUBTITLE, IT IS IN THE BEST INTEREST OF THE STATE FOR THE BOARD TO ESTABLISH A PROCESS FOR SETTING UPPER PAYMENT LIMITS FOR ~~ALL~~ PURCHASES AND PAYOR REIMBURSEMENTS OF PRESCRIPTION DRUG PRODUCTS IN THE STATE THAT THE BOARD DETERMINES HAVE LED OR WILL LEAD TO AN AFFORDABILITY CHALLENGE.

(2) WHEN MAKING A DETERMINATION UNDER PARAGRAPH (1) OF THIS SUBSECTION, THE BOARD SHALL CONSIDER, IF APPLICABLE:

(I) CONTRACT AND BUDGET DATA PROVIDED TO THE BOARD THAT DEMONSTRATES SAVINGS TO THE STATE OR LOCAL GOVERNMENTS AS A RESULT OF UPPER PAYMENT LIMITS SET IN ACCORDANCE WITH § 21–2C–14 OF THIS SUBTITLE;

(II) SUCCESS OF SETTING UPPER PAYMENT LIMITS IN OTHER STATES; AND

(III) EXPECTED SAVINGS FROM MEDICARE MAXIMUM FAIR PRICES SET BY THE CENTERS FOR MEDICARE AND MEDICAID SERVICES.

(B) (1) IF THE BOARD MAKES AN AFFIRMATIVE DETERMINATION UNDER SUBSECTION (A) OF THIS SECTION, THE BOARD, IN CONSULTATION WITH THE STAKEHOLDER COUNCIL, SHALL ESTABLISH A PROCESS FOR SETTING UPPER PAYMENT LIMITS FOR ~~ALL~~ PURCHASES AND PAYOR REIMBURSEMENTS OF PRESCRIPTION DRUG PRODUCTS IN THE STATE THAT THE BOARD DETERMINES HAVE LED OR WILL LEAD TO AN AFFORDABILITY CHALLENGE.

(2) THE PROCESS ESTABLISHED UNDER PARAGRAPH (1) OF THIS SUBSECTION SHALL:

(I) TO THE EXTENT APPROPRIATE, USE THE PLAN OF ACTION APPROVED UNDER § 21–2C–13(D) OF THIS SUBTITLE; AND

(II) OTHERWISE COMPLY WITH THE REQUIREMENTS FOR SETTING UPPER PAYMENT LIMITS ESTABLISHED UNDER THIS SUBTITLE.

(3) BEFORE ESTABLISHING AN UPPER PAYMENT LIMIT THAT APPLIES TO THE MARYLAND MEDICAL ASSISTANCE PROGRAM, THE BOARD SHALL CONFER WITH THE MARYLAND MEDICAL ASSISTANCE PROGRAM TO APPROVE THE APPLICATION OF THE UPPER PAYMENT LIMIT BY ASSESSING WHETHER THE PROPOSED UPPER PAYMENT LIMIT WILL:

(I) CONFLICT WITH THE MEDICAID DRUG REBATES PROGRAM, THE COVERED OUTPATIENT DRUG RULE (CMS–2345–FC), OR ANY OTHER FEDERAL REQUIREMENTS AS APPLICABLE; AND

(II) REQUIRE ADDITIONAL FUNDING TO BE ALLOCATED TO THE MARYLAND MEDICAL ASSISTANCE PROGRAM BUDGET.

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

Article – Health – General

21–2C–16.

(C) (1) ~~IF~~ SUBJECT TO PARAGRAPH (2) OF THIS SUBSECTION, IF THE BOARD ESTABLISHES A PROCESS UNDER SUBSECTION (B) OF THIS SECTION, THE BOARD SHALL SET UPPER PAYMENT LIMITS FOR ~~ALL~~ PURCHASES AND PAYOR REIMBURSEMENTS OF PRESCRIPTION DRUG PRODUCTS IN THE STATE IN ACCORDANCE WITH THE PROCESS.

(2) THIS SUBSECTION DOES NOT APPLY WITH RESPECT TO:

(I) PAYOR REIMBURSEMENTS UNDER MEDICARE PART C AND D PLANS;

(II) PURCHASES UNDER THE FEDERAL 340B DRUG PRICING PROGRAM; AND

(III) PURCHASES AND PAYOR REIMBURSEMENTS ~~UNDER~~ *BY FEDERAL AGENCIES OR* FEDERAL PROGRAMS THAT ~~ARE~~ *THE STATE IS* PREEMPTED *FROM REGULATING* BY FEDERAL LAW ~~INCLUDING:~~

~~1. THE DEPARTMENT OF DEFENSE;~~

~~2. THE DEPARTMENT OF VETERANS AFFAIRS;~~

~~3. THE PUBLIC HEALTH SERVICE;~~

~~4. THE UNITED STATES COAST GUARD;~~

~~5. TRICARE;~~

~~6. THE FEDERAL EMPLOYEES HEALTH BENEFIT PLAN; AND~~

~~7. ANY OTHER EXCLUSIVE FEDERAL PROGRAM AS APPLICABLE.~~

SECTION 3. AND BE IT FURTHER ENACTED, That:

(a) Section 2 of this Act is contingent on the Prescription Drug Affordability Board setting upper payment limits on two prescription drugs in accordance with § 21–2C–14 of the Health – General Article, as enacted by Section 1 of this Act, and each upper payment limit being in effect for 1 year.

(b) Within 5 days after the conditions described in subsection (a) of this section are met, the Prescription Drug Affordability Board shall notify the Department of Legislative Services.

(c) If notice is received by the Department of Legislative Services in accordance with subsection (b) of this section on or before ~~September 31~~ September 30, 2030, Section 2 of this Act shall take effect on the date the notice is received by the Department of Legislative Services.

(d) If notice is not received by the Department of Legislative Services on or before ~~December 31~~ September 30, 2030, Section 2 of this Act, with no further action required by the General Assembly, shall be null and void.

SECTION 4. AND BE IT FURTHER ENACTED, That, subject to Section 3 of this Act, this Act shall take effect October 1, 2025.

Approved by the Governor, May 20, 2025.