Chapter 40

(Senate Bill 202)

AN ACT concerning

Prescription Drug Affordability Board – Upper Payment Limits

FOR the purpose of reestablishing the requirement that the Prescription Drug Affordability Board, under certain circumstances, draft a plan of action for implementing a process to set upper payment limits for prescription drug products that it determines have led or will lead to affordability challenges; reestablishing the authority of the Board to set upper payment limits, under certain circumstances, for prescription drug products that are purchased or paid for by or through certain State or local government entities, plans, or programs; reestablishing a certain appeals process for persons aggrieved by an upper payment limit set by the Board; reestablishing the requirement that the Board submit a report to certain committees of the General Assembly recommending whether the General Assembly should expand the Board's authority to set upper payment limits to all purchases and payor reimbursements of prescription drug products in the State; and generally relating to the setting of upper payment limits by the Prescription Drug Affordability Board.

BY adding to

Article – Health – General Section 21–2C–13 through 21–2C–16 Annotated Code of Maryland (2019 Replacement Volume and 2022 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-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:

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(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, 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:

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(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, THE BOARD 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-15.

(A) A PERSON AGGRIEVED BY AN UPPER PAYMENT LIMIT SET BY THE BOARD MAY REQUEST AN APPEAL WITHIN 30 DAYS AFTER THE BOARD MAKES THE DECISION TO SET THE LIMIT.

(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 ISSUED UNDER SUBSECTION (B) OF THIS SECTION MAY PETITION FOR JUDICIAL REVIEW AS PROVIDED BY THE ADMINISTRATIVE PROCEDURE ACT.

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.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act is an emergency measure, is necessary for the immediate preservation of the public health or safety, has been passed by a yea and nay vote supported by three–fifths of all the members elected to each of the two Houses of the General Assembly, and shall take effect from the date it is

enacted.

Approved by the Governor, April 11, 2023.