SENATE BILL 405

C3 9lr1091
CF HB 435

By: **Senators Hayes, Beidle, Feldman, Hershey, Klausmeier, Kramer, and Reilly**
Introduced and read first time: January 31, 2019
Assigned to: Finance

A BILL ENTITLED

AN ACT concerning

Health Insurance – Prescription Drugs – Formulary Changes

FOR the purpose of prohibiting certain insurers, nonprofit health service plans, and health maintenance organizations from making certain formulary changes during certain time periods, except under certain circumstances; defining a certain term; providing for the application of this Act; and generally relating to formulary changes for prescription drugs.

BY repealing and reenacting, with amendments,
Article – Insurance
Section 15–831
Annotated Code of Maryland
(2017 Replacement Volume and 2018 Supplement)

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

Article – Insurance

15–831.

(a) (1) In this section the following words have the meanings indicated.

(2) "Authorized prescriber" has the meaning stated in § 12–101 of the Health Occupations Article.

(3) "Formulary" means a list of prescription drugs or devices that are covered by an entity subject to this section.

(4) (i) "Member" means an individual entitled to health care benefits for prescription drugs or devices under a policy issued or delivered in the State by an entity

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

subject to this section.

(ii) "Member" includes a subscriber.

(5) (I) "UTILIZATION MANAGEMENT RESTRICTION" MEANS A RESTRICTION ON COVERAGE FOR A PRESCRIPTION DRUG ON A FORMULARY.

(II) "UTILIZATION MANAGEMENT RESTRICTION" INCLUDES:

1. IMPOSING OR ALTERING A QUANTITY LIMIT FOR A PRESCRIPTION DRUG;

2. ADDING A REQUIREMENT THAT AN ENROLLEE RECEIVE A PRIOR AUTHORIZATION FOR A PRESCRIPTION DRUG; AND

3. IMPOSING A STEP THERAPY PROTOCOL RESTRICTION FOR A PRESCRIPTION DRUG.

(b) (1) This section applies to:

(i) insurers and nonprofit health service plans that provide coverage for prescription drugs and devices under individual, group, or blanket health insurance policies or contracts that are issued or delivered in the State; and

(ii) health maintenance organizations that provide coverage for prescription drugs and devices under individual or group contracts that are issued or delivered in the State.

(2) An insurer, nonprofit health service plan, or health maintenance organization that provides coverage for prescription drugs and devices through a pharmacy benefit manager is subject to the requirements of this section.

(3) This section does not apply to a managed care organization as defined in § 15–101 of the Health – General Article.

(C) (1) EXCEPT AS PROVIDED IN PARAGRAPH (2) OF THIS SUBSECTION, DURING A PLAN YEAR AND THE OPEN ENROLLMENT PERIOD THAT PRECEDES THE PLAN YEAR, AN ENTITY SUBJECT TO THIS SECTION MAY NOT:

(I) REMOVE A PRESCRIPTION DRUG FROM A FORMULARY;

(II) IF A GENERIC EQUIVALENT IS NOT AVAILABLE AND THE FORMULARY INCLUDES TWO OR MORE BENEFIT TIERS THAT ESTABLISH DIFFERENT DEDUCTIBLE, COPAYMENT, OR COINSURANCE REQUIREMENTS FOR PRESCRIPTION DRUGS IN EACH BENEFIT TIER, MOVE A PRESCRIPTION DRUG TO A BENEFIT TIER

THAT REQUIRES A MEMBER TO PAY A HIGHER DEDUCTIBLE, COPAYMENT, OR COINSURANCE AMOUNT FOR THE PRESCRIPTION DRUG; OR

(III) ADD A UTILIZATION MANAGEMENT RESTRICTION TO A PRESCRIPTION DRUG IN THE FORMULARY.

(2) AN ENTITY SUBJECT TO THIS SECTION MAY REMOVE A PRESCRIPTION DRUG FROM A FORMULARY OR IMPOSE A UTILIZATION MANAGEMENT RESTRICTION IF AT ANY TIME:

(I) THE U.S. FOOD AND DRUG ADMINISTRATION ISSUES A NOTICE, GUIDANCE, WARNING, ANNOUNCEMENT, OR ANY OTHER STATEMENT ABOUT THE PRESCRIPTION DRUG THAT CALLS INTO QUESTION THE CLINICAL SAFETY OF THE PRESCRIPTION DRUG;

(II) THE MANUFACTURER OF THE PRESCRIPTION DRUG HAS NOTIFIED THE U.S. FOOD AND DRUG ADMINISTRATION OF A POTENTIAL OR PERMANENT DISCONTINUANCE OR AN INTERRUPTION IN MANUFACTURING OF THE PRESCRIPTION DRUG; OR

(III) THE PRESCRIPTION DRUG IS APPROVED BY THE U.S. FOOD AND DRUG ADMINISTRATION FOR USE WITHOUT A PRESCRIPTION.

(3) THIS SUBSECTION DOES NOT PROHIBIT AN ENTITY SUBJECT TO THIS SECTION FROM:

(I) ADDING A PRESCRIPTION DRUG TO A FORMULARY AT ANY TIME; OR

(II) MODIFYING A FORMULARY AT THE TIME OF RENEWAL AND BEFORE THE OPEN ENROLLMENT PERIOD IF, NO LATER THAN 60 DAYS BEFORE THE MODIFICATION IS EFFECTIVE, THE ENTITY:

1. PROVIDES WRITTEN NOTICE OF THE MODIFICATION TO THE AFFECTED MEMBER AND THE AFFECTED MEMBER'S AUTHORIZED PRESCRIBER; AND

2. POSTS THE MODIFICATION ON THE ENTITY'S ONLINE FORMULARY.

[(c)**] (D)** Each entity subject to this section that limits its coverage of prescription drugs or devices to those in a formulary shall establish and implement a procedure by which a member may receive a prescription drug or device that is not in the entity's formulary in accordance with this section.

[(d)**] (E)** The procedure shall provide for coverage for a prescription drug or device that is not in the formulary if, in the judgment of the authorized prescriber:

(1) there is no equivalent prescription drug or device in the entity's formulary;

(2) an equivalent prescription drug or device in the entity's formulary:

(i) has been ineffective in treating the disease or condition of the member; or

(ii) has caused or is likely to cause an adverse reaction or other harm to the member; or

(3) for a contraceptive prescription drug or device, the prescription drug or device that is not on the formulary is medically necessary for the member to adhere to the appropriate use of the prescription drug or device.

[(e)**] (F)** A decision by an entity subject to this section not to provide access to or coverage of a prescription drug or device in accordance with this section constitutes an adverse decision as defined under Subtitle 10A of this title if the decision is based on a finding that the proposed drug or device is not medically necessary, appropriate, or efficient.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall apply to all policies, contracts, and health benefit plans issued, delivered, or renewed in the State on or after January 1, 2020.

SECTION 3. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2019.