

# HOUSE BILL 435

C3

9lr1092  
CF SB 405

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By: **Delegates Kelly, Bagnall, Bromwell, Hill, Metzgar, Morgan, Saab, Valentino-Smith, and K. Young**

Introduced and read first time: January 31, 2019

Assigned to: Health and Government Operations

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Committee Report: Favorable with amendments

House action: Adopted

Read second time: March 12, 2019

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## CHAPTER \_\_\_\_\_

1 AN ACT concerning

### 2 **Health Insurance – Prescription Drugs – Formulary Changes**

3 FOR the purpose of ~~prohibiting certain insurers, nonprofit health service plans, and health~~  
4 ~~maintenance organizations from making certain formulary changes during certain~~  
5 ~~time periods, except under certain circumstances; defining a certain term; requiring~~  
6 certain entities to establish and implement a procedure by which a member may  
7 receive a prescription drug or device that has been removed from a certain entity's  
8 formulary or a member may continue the same cost sharing requirements under  
9 certain circumstances; altering the requirement that a certain entity provide  
10 coverage for a prescription drug or device under certain circumstances; requiring a  
11 certain entity to provide a certain member with a certain notice; providing for the  
12 application of this Act; and generally relating to formulary changes for prescription  
13 drugs.

14 BY repealing and reenacting, with amendments,

15 Article – Insurance

16 Section 15–831

17 Annotated Code of Maryland

18 (2017 Replacement Volume and 2018 Supplement)

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

### 21 **Article – Insurance**

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EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.

Underlining indicates amendments to bill.

~~Strike out~~ indicates matter stricken from the bill by amendment or deleted from the law by amendment.



1 15-831.

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

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

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

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

10 (ii) "Member" includes a subscriber.

11 ~~(5) (i) "UTILIZATION MANAGEMENT RESTRICTION" MEANS A~~  
12 ~~RESTRICTION ON COVERAGE FOR A PRESCRIPTION DRUG ON A FORMULARY.~~

13 ~~(ii) "UTILIZATION MANAGEMENT RESTRICTION" INCLUDES:~~

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

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

18 ~~3. IMPOSING A STEP THERAPY PROTOCOL RESTRICTION~~  
19 ~~FOR A PRESCRIPTION DRUG.~~

20 (b) (1) This section applies to:

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

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

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

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

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

6                   ~~(i) REMOVE A PRESCRIPTION DRUG FROM A FORMULARY;~~

7                   ~~(ii) IF A GENERIC EQUIVALENT IS NOT AVAILABLE AND THE~~  
8 ~~FORMULARY INCLUDES TWO OR MORE BENEFIT TIERS THAT ESTABLISH DIFFERENT~~  
9 ~~DEDUCTIBLE, COPAYMENT, OR COINSURANCE REQUIREMENTS FOR PRESCRIPTION~~  
10 ~~DRUGS IN EACH BENEFIT TIER, MOVE A PRESCRIPTION DRUG TO A BENEFIT TIER~~  
11 ~~THAT REQUIRES A MEMBER TO PAY A HIGHER DEDUCTIBLE, COPAYMENT, OR~~  
12 ~~COINSURANCE AMOUNT FOR THE PRESCRIPTION DRUG; OR~~

13                   ~~(iii) ADD A UTILIZATION MANAGEMENT RESTRICTION TO A~~  
14 ~~PRESCRIPTION DRUG IN THE FORMULARY.~~

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

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

22                   ~~(ii) THE MANUFACTURER OF THE PRESCRIPTION DRUG HAS~~  
23 ~~NOTIFIED THE U.S. FOOD AND DRUG ADMINISTRATION OF A POTENTIAL OR~~  
24 ~~PERMANENT DISCONTINUANCE OR AN INTERRUPTION IN MANUFACTURING OF THE~~  
25 ~~PRESCRIPTION DRUG; OR~~

26                   ~~(iii) THE PRESCRIPTION DRUG IS APPROVED BY THE U.S. FOOD~~  
27 ~~AND DRUG ADMINISTRATION FOR USE WITHOUT A PRESCRIPTION.~~

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

30                   ~~(i) ADDING A PRESCRIPTION DRUG TO A FORMULARY AT ANY~~  
31 ~~TIME; OR~~

~~(H) 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:

(1) receive a prescription drug or device that is not in the entity's formulary OR HAS BEEN REMOVED FROM THE ENTITY'S FORMULARY in accordance with this section; OR

(2) CONTINUE THE SAME COST SHARING REQUIREMENTS IF THE ENTITY HAS MOVED THE PRESCRIPTION DRUG OR DEVICE TO A HIGHER DEDUCTIBLE, COPAYMENT, OR COINSURANCE TIER.

~~(d) (E)~~ The procedure shall provide for coverage for a prescription drug or device ~~that is not in the formulary~~ IN ACCORDANCE WITH SUBSECTION (C) OF THIS SECTION if, in the judgment of the authorized prescriber:

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

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

(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

1 adverse decision as defined under Subtitle 10A of this title if the decision is based on a  
2 finding that the proposed drug or device is not medically necessary, appropriate, or  
3 efficient.

4 **(F) AN ENTITY SUBJECT TO THIS SECTION THAT REMOVES A DRUG FROM ITS**  
5 **FORMULARY OR MOVES A PRESCRIPTION DRUG OR DEVICE TO A BENEFIT TIER THAT**  
6 **REQUIRES A MEMBER TO PAY A HIGHER DEDUCTIBLE, COPAYMENT, OR**  
7 **COINSURANCE AMOUNT FOR THE PRESCRIPTION DRUG OR DEVICE SHALL PROVIDE**  
8 **A MEMBER WHO IS CURRENTLY ON THE PRESCRIPTION DRUG OR DEVICE AND THE**  
9 **MEMBER’S HEALTH CARE PROVIDER WITH:**

10 **(1) NOTICE OF THE CHANGE AT LEAST 30 DAYS BEFORE THE CHANGE**  
11 **IS IMPLEMENTED; AND**

12 **(2) IN THE NOTICE REQUIRED UNDER ITEM (1) OF THIS SUBSECTION,**  
13 **THE PROCESS FOR REQUESTING AN EXEMPTION THROUGH THE PROCEDURE**  
14 **ADOPTED IN ACCORDANCE WITH THIS SECTION.**

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

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

Approved:

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Governor.

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Speaker of the House of Delegates.

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President of the Senate.