

SENATE BILL 515

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By: **Senator Lam**

Introduced and read first time: February 3, 2023

Assigned to: Finance

A BILL ENTITLED

1 AN ACT concerning

2 **Health Insurance – Step Therapy or Fail–First Protocol – Revisions**

3 FOR the purpose of prohibiting certain insurers, nonprofit health service plans, and health
4 maintenance organizations from imposing a step therapy or fail–first protocol on an
5 insured or an enrollee for certain prescription drugs used to treat a certain mental
6 disorder or condition; requiring certain insurers, nonprofit health service plans, or
7 health maintenance organizations to establish a certain process for requesting an
8 exception to a step therapy or fail–first protocol; and generally relating to step
9 therapy or fail–first protocols and health insurance.

10 BY repealing and reenacting, with amendments,
11 Article – Insurance
12 Section 15–142
13 Annotated Code of Maryland
14 (2017 Replacement Volume and 2022 Supplement)

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

17 **Article – Insurance**

18 15–142.

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

20 (2) “Step therapy drug” means a prescription drug or sequence of
21 prescription drugs required to be used under a step therapy or fail–first protocol.

22 (3) **“STEP THERAPY EXCEPTION REQUEST” MEANS A REQUEST TO**
23 **OVERRIDE A STEP THERAPY OR FAIL–FIRST PROTOCOL.**

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 ~~[(3)]~~ **(4)** **(I)** “Step therapy or fail–first protocol” means a protocol
2 established by an insurer, a nonprofit health service plan, or a health maintenance
3 organization that requires a prescription drug or sequence of prescription drugs to be used
4 by an insured or an enrollee before a prescription drug ordered by a prescriber for the
5 insured or the enrollee is covered.

6 **(II)** “**STEP THERAPY OR FAIL–FIRST PROTOCOL**” INCLUDES A
7 **PROTOCOL THAT MEETS THE DEFINITION UNDER SUBPARAGRAPH (I) OF THIS**
8 **PARAGRAPH REGARDLESS OF THE NAME, LABEL, OR TERMINOLOGY USED BY THE**
9 **INSURER, NONPROFIT HEALTH SERVICE PLAN, OR HEALTH MAINTENANCE**
10 **ORGANIZATION TO IDENTIFY THE PROTOCOL.**

11 ~~[(4)]~~ **(5)** “Supporting medical information” means:

12 (i) a paid claim from an entity subject to this section for an insured
13 or an enrollee;

14 (ii) a pharmacy record that documents that a prescription has been
15 filled and delivered to an insured or an enrollee, or a representative of an insured or an
16 enrollee; or

17 (iii) other information mutually agreed on by an entity subject to this
18 section and the prescriber of an insured or an enrollee.

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

20 (i) insurers and nonprofit health service plans that provide hospital,
21 medical, or surgical benefits to individuals or groups on an expense–incurred basis under
22 health insurance policies or contracts that are issued or delivered in the State; and

23 (ii) health maintenance organizations that provide hospital,
24 medical, or surgical benefits to individuals or groups under contracts that are issued or
25 delivered in the State.

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

29 (c) An entity subject to this section may not impose a step therapy or fail–first
30 protocol on an insured or an enrollee if:

31 (1) the step therapy drug has not been approved by the U.S. Food and Drug
32 Administration for the medical condition being treated; or

1 (2) a prescriber provides supporting medical information to the entity that
2 a prescription drug covered by the entity:

3 (i) was ordered by a prescriber for the insured or enrollee within the
4 past 180 days; and

5 (ii) based on the professional judgment of the prescriber, was
6 effective in treating the insured's or enrollee's disease or medical condition.

7 (d) Subsection (c) of this section may not be construed to require coverage for a
8 prescription drug that is not:

9 (1) covered by the policy or contract of an entity subject to this section; or

10 (2) otherwise required by law to be covered.

11 (e) An entity subject to this section may not impose a step therapy or fail-first
12 protocol on an insured or an enrollee for a prescription drug approved by the U.S. Food and
13 Drug Administration if:

14 (1) **(I)** the prescription drug is used to treat the insured's or enrollee's
15 stage four advanced metastatic cancer; and

16 **[(2)] (II)** use of the prescription drug is:

17 **[(i)] 1.** consistent with the U.S. Food and Drug
18 Administration-approved indication or the National Comprehensive Cancer Network
19 Drugs & Biologics Compendium indication for the treatment of stage four advanced
20 metastatic cancer; and

21 **[(ii)] 2.** supported by peer-reviewed medical literature; **OR**

22 **(2) THE PRESCRIPTION DRUG IS USED TO TREAT THE INSURED'S OR**
23 **ENROLLEE'S MENTAL DISORDER OR CONDITION, AS DEFINED IN THE CURRENT**
24 **DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS PUBLISHED BY**
25 **THE AMERICAN PSYCHIATRIC ASSOCIATION, THAT RESULTS IN A SERIOUS**
26 **FUNCTIONAL IMPAIRMENT THAT SUBSTANTIALLY INTERFERES WITH OR LIMITS ONE**
27 **OR MORE MAJOR LIFE ACTIVITIES.**

28 **(F) (1) AN ENTITY SUBJECT TO THIS SECTION SHALL ESTABLISH A**
29 **PROCESS FOR REQUESTING AN EXCEPTION TO A STEP THERAPY OR FAIL-FIRST**
30 **PROTOCOL THAT IS:**

31 **(I) CLEARLY DESCRIBED, INCLUDING THE SPECIFIC**
32 **INFORMATION AND DOCUMENTATION THAT MUST BE SUBMITTED BY THE**

1 **PRESCRIBER TO BE CONSIDERED A COMPLETE STEP THERAPY EXCEPTION**
2 **REQUEST;**

3 **(II) EASILY ACCESSIBLE TO THE PRESCRIBER; AND**

4 **(III) POSTED ON THE ENTITY'S WEBSITE.**

5 **(2) A STEP THERAPY EXCEPTION REQUEST SHALL BE GRANTED IF,**
6 **BASED ON THE PROFESSIONAL JUDGMENT OF THE PRESCRIBER:**

7 **(I) THE STEP THERAPY DRUG IS CONTRAINDICATED OR WILL**
8 **LIKELY CAUSE AN ADVERSE REACTION, PHYSICAL HARM, OR MENTAL HARM TO THE**
9 **INSURED OR ENROLLEE;**

10 **(II) THE STEP THERAPY DRUG IS EXPECTED TO BE INEFFECTIVE**
11 **BASED ON THE KNOWN CLINICAL CHARACTERISTICS OF THE INSURED OR ENROLLEE**
12 **AND THE KNOWN CHARACTERISTICS OF THE PRESCRIPTION DRUG REGIMEN;**

13 **(III) THE INSURED OR ENROLLEE IS STABLE ON A PRESCRIPTION**
14 **DRUG PRESCRIBED FOR THE MEDICAL CONDITION UNDER CONSIDERATION WHILE**
15 **COVERED UNDER THE POLICY OR CONTRACT OF THE ENTITY OR UNDER A PREVIOUS**
16 **SOURCE OF COVERAGE; OR**

17 **(IV) WHILE COVERED UNDER THE POLICY OR CONTRACT OF THE**
18 **ENTITY OR A PREVIOUS SOURCE OF COVERAGE, THE INSURED OR ENROLLEE HAS**
19 **TRIED A PRESCRIPTION DRUG THAT:**

20 **1. IS IN THE SAME PHARMACOLOGIC CLASS OR HAS THE**
21 **SAME MECHANISM OF ACTION AS THE STEP THERAPY DRUG; AND**

22 **2. WAS DISCONTINUED BY THE PRESCRIBER DUE TO**
23 **LACK OF EFFICACY OR EFFECTIVENESS, DIMINISHED EFFECT, OR AN ADVERSE**
24 **EVENT.**

25 **(3) AN INSURED OR ENROLLEE MAY APPEAL THE DECISION TO DENY**
26 **A STEP THERAPY EXCEPTION REQUEST UNDER THIS SECTION.**

27 **(4) (I) A STEP THERAPY EXCEPTION REQUEST OR APPEAL SHALL**
28 **BE GRANTED:**

29 **1. IN REAL TIME IF NO ADDITIONAL INFORMATION IS**
30 **NEEDED BY THE ENTITY TO PROCESS THE REQUEST AND THE REQUEST MEETS THE**
31 **ENTITY'S CRITERIA FOR APPROVAL; OR**

1 **2. IF ADDITIONAL INFORMATION IS NEEDED BY THE**
2 **ENTITY TO PROCESS THE REQUEST AND THE REQUEST IS NOT URGENT, WITHIN 1**
3 **BUSINESS DAY AFTER THE ENTITY RECEIVES ALL RELEVANT INFORMATION NEEDED**
4 **TO PROCESS THE REQUEST.**

5 **(II) IF AN ENTITY SUBJECT TO THIS SECTION DOES NOT GRANT**
6 **OR DENY A STEP THERAPY EXCEPTION REQUEST OR AN APPEAL WITHIN THE TIME**
7 **PERIOD REQUIRED UNDER SUBPARAGRAPH (I) OF THIS PARAGRAPH, THE REQUEST**
8 **OR APPEAL SHALL BE TREATED AS GRANTED.**

9 **(5) THIS SUBSECTION MAY NOT BE CONSTRUED TO PREVENT:**

10 **(I) AN ENTITY SUBJECT TO THIS SECTION FROM REQUIRING AN**
11 **INSURED OR ENROLLEE TO TRY AN AB-RATED GENERIC EQUIVALENT OR**
12 **INTERCHANGEABLE BIOLOGICAL PRODUCT BEFORE PROVIDING COVERAGE FOR**
13 **THE EQUIVALENT BRANDED PRESCRIPTION DRUG; OR**

14 **(II) A HEALTH CARE PROVIDER FROM PRESCRIBING A**
15 **PRESCRIPTION DRUG THAT IS DETERMINED TO BE MEDICALLY APPROPRIATE.**

16 **(6) AN ENTITY SUBJECT TO THIS SECTION MAY USE AN EXISTING STEP**
17 **THERAPY EXCEPTION PROCESS THAT SATISFIES THE REQUIREMENTS UNDER THIS**
18 **SUBSECTION.**

19 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall apply to all
20 policies, contracts, and health benefit plans issued, delivered, or renewed in the State on or
21 after January 1, 2024.

22 SECTION 3. AND BE IT FURTHER ENACTED, That this Act shall take effect
23 January 1, 2024.