

HOUSE BILL 785

J5, J4

3lr1212
CF SB 515

By: Delegates S. Johnson and White, White, Alston, Bagnall, Bhandari, Chisholm, Cullison, Guzzone, Hill, Hutchinson, Kaiser, Kerr, R. Lewis, Lopez, Martinez, M. Morgan, Pena-Melnyk, Reilly, Rosenberg, Szeliga, Taveras, and Woods

Introduced and read first time: February 8, 2023
Assigned to: Health and Government Operations

Committee Report: Favorable with amendments
House action: Adopted
Read second time: March 10, 2023

CHAPTER _____

1 AN ACT concerning

2 **Health Insurance – Step Therapy or Fail-First Protocol and Prior Authorization**
3 **– Revisions**

4 FOR the purpose of ~~prohibiting certain insurers, nonprofit health service plans, and health~~
5 ~~maintenance organizations from imposing a step therapy or fail-first protocol on an~~
6 ~~insured or an enrollee for certain prescription drugs used to treat a certain mental~~
7 ~~disorder or condition;~~ requiring certain insurers, nonprofit health service plans, or
8 health maintenance organizations to establish a certain process for requesting an
9 exception to a step therapy or fail-first protocol; prohibiting certain insurers,
10 nonprofit health service plans, health maintenance organizations, and pharmacy
11 benefits managers from requiring more than a certain number of prior
12 authorizations for a prescription for different dosages of the same prescription drug;
13 requiring a private review agent to make a determination on a step therapy
14 exception request or prior authorization request submitted electronically within a
15 certain period of time; and generally relating to step therapy or fail-first protocols
16 and prior authorizations and health insurance.

17 BY repealing and reenacting, with amendments,
18 Article – Insurance
19 Section 15-142 and 15-10B-06(a)
20 Annotated Code of Maryland
21 (2017 Replacement Volume and 2022 Supplement)

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 BY repealing and reenacting, without amendments,
 2 Article – Insurance
 3 Section 15–854(a)
 4 Annotated Code of Maryland
 5 (2017 Replacement Volume and 2022 Supplement)

6 BY adding to
 7 Article – Insurance
 8 Section 15–854(g)
 9 Annotated Code of Maryland
 10 (2017 Replacement Volume and 2022 Supplement)

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

13 **Article – Insurance**

14 15–142.

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

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

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

20 [(3)] (4) (I) “Step therapy or fail–first protocol” means a protocol
 21 established by an insurer, a nonprofit health service plan, or a health maintenance
 22 organization that requires a prescription drug or sequence of prescription drugs to be used
 23 by an insured or an enrollee before a prescription drug ordered by a prescriber for the
 24 insured or the enrollee is covered.

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

30 [(4)] (5) “Supporting medical information” means:

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

1 (ii) a pharmacy record that documents that a prescription has been
2 filled and delivered to an insured or an enrollee, or a representative of an insured or an
3 enrollee; or

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 (1) ~~(H)~~ the prescription drug is used to treat the insured's or enrollee's
2 stage four advanced metastatic cancer; and

3 ~~{(2)}~~ ~~(H)~~ use of the prescription drug is:

4 ~~{(i)}~~ ~~1.~~ consistent with the U.S. Food and Drug
5 Administration–approved indication or the National Comprehensive Cancer Network
6 Drugs & Biologics Compendium indication for the treatment of stage four advanced
7 metastatic cancer; and

8 ~~{(ii)}~~ ~~2.~~ supported by peer–reviewed medical literature; ~~OR~~

9 ~~(2) THE PRESCRIPTION DRUG IS USED TO TREAT THE INSURED'S OR~~
10 ~~ENROLLEE'S MENTAL DISORDER OR CONDITION, AS DEFINED IN THE CURRENT~~
11 ~~DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS PUBLISHED BY~~
12 ~~THE AMERICAN PSYCHIATRIC ASSOCIATION, THAT RESULTS IN A SERIOUS~~
13 ~~FUNCTIONAL IMPAIRMENT THAT SUBSTANTIALLY INTERFERES WITH OR LIMITS ONE~~
14 ~~OR MORE MAJOR LIFE ACTIVITIES.~~

15 (F) (1) AN ENTITY SUBJECT TO THIS SECTION SHALL ESTABLISH A
16 PROCESS FOR REQUESTING AN EXCEPTION TO A STEP THERAPY OR FAIL–FIRST
17 PROTOCOL THAT IS:

18 (I) CLEARLY DESCRIBED, INCLUDING THE SPECIFIC
19 INFORMATION AND DOCUMENTATION, IF NEEDED, THAT MUST BE SUBMITTED BY
20 THE PRESCRIBER TO BE CONSIDERED A COMPLETE STEP THERAPY EXCEPTION
21 REQUEST;

22 (II) EASILY ACCESSIBLE TO THE PRESCRIBER; AND

23 (III) POSTED ON THE ENTITY'S WEBSITE.

24 (2) A STEP THERAPY EXCEPTION REQUEST SHALL BE GRANTED IF,
25 BASED ON THE PROFESSIONAL JUDGMENT OF THE PRESCRIBER AND ANY
26 INFORMATION AND DOCUMENTATION REQUIRED UNDER PARAGRAPH (1)(I) OF THIS
27 SUBSECTION:

28 (I) THE STEP THERAPY DRUG IS CONTRAINDICATED OR WILL
29 LIKELY CAUSE AN ADVERSE REACTION, ~~PHYSICAL HARM, OR MENTAL HARM~~ TO THE
30 INSURED OR ENROLLEE;

31 (II) THE STEP THERAPY DRUG IS EXPECTED TO BE INEFFECTIVE
32 BASED ON THE KNOWN CLINICAL CHARACTERISTICS OF THE INSURED OR ENROLLEE
33 AND THE KNOWN CHARACTERISTICS OF THE PRESCRIPTION DRUG REGIMEN;

1 (III) THE INSURED OR ENROLLEE IS STABLE ON A PRESCRIPTION
2 DRUG PRESCRIBED FOR THE MEDICAL CONDITION UNDER CONSIDERATION WHILE
3 COVERED UNDER THE POLICY OR CONTRACT OF THE ENTITY OR UNDER A PREVIOUS
4 SOURCE OF COVERAGE; OR

5 (IV) WHILE COVERED UNDER THE POLICY OR CONTRACT OF THE
6 ENTITY OR A PREVIOUS SOURCE OF COVERAGE, THE INSURED OR ENROLLEE HAS
7 TRIED A PRESCRIPTION DRUG THAT:

8 1. IS IN THE SAME PHARMACOLOGIC CLASS OR HAS THE
9 SAME MECHANISM OF ACTION AS THE STEP THERAPY DRUG; AND

10 2. WAS DISCONTINUED BY THE PRESCRIBER DUE TO
11 LACK OF EFFICACY OR EFFECTIVENESS, DIMINISHED EFFECT, OR AN ADVERSE
12 EVENT.

13 ~~(3) AN INSURED OR ENROLLEE MAY APPEAL THE DECISION TO DENY~~
14 ~~A STEP THERAPY EXCEPTION REQUEST UNDER THIS SECTION.~~

15 ~~(4) (i) A STEP THERAPY EXCEPTION REQUEST OR APPEAL SHALL~~
16 ~~BE GRANTED:~~

17 ~~1. IN REAL TIME IF NO ADDITIONAL INFORMATION IS~~
18 ~~NEEDED BY THE ENTITY TO PROCESS THE REQUEST AND THE REQUEST MEETS THE~~
19 ~~ENTITY'S CRITERIA FOR APPROVAL; OR~~

20 ~~2. IF ADDITIONAL INFORMATION IS NEEDED BY THE~~
21 ~~ENTITY TO PROCESS THE REQUEST AND THE REQUEST IS NOT URGENT, WITHIN 1~~
22 ~~BUSINESS DAY AFTER THE ENTITY RECEIVES ALL RELEVANT INFORMATION NEEDED~~
23 ~~TO PROCESS THE REQUEST.~~

24 ~~(ii) IF AN ENTITY SUBJECT TO THIS SECTION DOES NOT GRANT~~
25 ~~OR DENY A STEP THERAPY EXCEPTION REQUEST OR AN APPEAL WITHIN THE TIME~~
26 ~~PERIOD REQUIRED UNDER SUBPARAGRAPH (i) OF THIS PARAGRAPH, THE REQUEST~~
27 ~~OR APPEAL SHALL BE TREATED AS GRANTED.~~

28 (3) ON GRANTING A STEP THERAPY EXCEPTION REQUEST, AN ENTITY
29 SUBJECT TO THIS SECTION SHALL AUTHORIZE COVERAGE FOR THE PRESCRIPTION
30 DRUG ORDERED BY THE PRESCRIBER FOR AN INSURED OR ENROLLEE.

31 (4) AN ENROLLEE OR INSURED MAY APPEAL A STEP THERAPY
32 EXCEPTION REQUEST DENIAL IN ACCORDANCE WITH SUBTITLE 10A OR SUBTITLE
33 10B OF THIS TITLE.

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

2 **(I) PREVENT:**

3 **1. AN ENTITY SUBJECT TO THIS SECTION FROM**
 4 **REQUIRING AN INSURED OR ENROLLEE TO TRY AN AB-RATED GENERIC**
 5 **EQUIVALENT OR INTERCHANGEABLE BIOLOGICAL PRODUCT BEFORE PROVIDING**
 6 **COVERAGE FOR THE EQUIVALENT BRANDED PRESCRIPTION DRUG; OR**

7 **~~(H)~~ 2. A HEALTH CARE PROVIDER FROM PRESCRIBING A**
 8 **PRESCRIPTION DRUG THAT IS DETERMINED TO BE MEDICALLY APPROPRIATE; OR**

9 **(II) REQUIRE AN ENTITY SUBJECT TO THIS SECTION TO**
 10 **PROVIDE COVERAGE FOR A PRESCRIPTION DRUG THAT IS NOT COVERED BY A**
 11 **POLICY OR CONTRACT OF THE ENTITY.**

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

15 15-854.

16 (a) (1) This section applies to:

17 (i) insurers and nonprofit health service plans that provide coverage
 18 for prescription drugs through a pharmacy benefit under individual, group, or blanket
 19 health insurance policies or contracts that are issued or delivered in the State; and

20 (ii) health maintenance organizations that provide coverage for
 21 prescription drugs through a pharmacy benefit under individual or group contracts that
 22 are issued or delivered in the State.

23 (2) An insurer, a nonprofit health service plan, or a health maintenance
 24 organization that provides coverage for prescription drugs through a pharmacy benefits
 25 manager or that contracts with a private review agent under Subtitle 10B of this article is
 26 subject to the requirements of this section.

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

29 **(G) (1) EXCEPT AS PROVIDED IN PARAGRAPH (2) OF THIS SUBSECTION,**
 30 **AN ENTITY SUBJECT TO THIS SECTION MAY NOT REQUIRE MORE THAN ONE PRIOR**
 31 **AUTHORIZATION IF TWO OR MORE TABLETS OF DIFFERENT DOSAGE STRENGTHS OF**
 32 **THE SAME PRESCRIPTION DRUG ARE:**

1 **(I) PRESCRIBED AT THE SAME TIME AS PART OF AN INSURED'S**
2 **TREATMENT PLAN; AND**

3 **(II) MANUFACTURED BY THE SAME MANUFACTURER.**

4 **(2) THIS SUBSECTION DOES NOT PROHIBIT AN ENTITY FROM**
5 **REQUIRING MORE THAN ONE PRIOR AUTHORIZATION IF THE PRESCRIPTION IS FOR**
6 **TWO OR MORE TABLETS OF DIFFERENT DOSAGE STRENGTHS OF AN OPIOID THAT IS**
7 **NOT AN OPIOID PARTIAL AGONIST.**

8 15-10B-06.

9 (a) (1) **[A] EXCEPT AS PROVIDED IN PARAGRAPH (4) OF THIS**
10 **SUBSECTION, A private review agent shall:**

11 (i) make all initial determinations on whether to authorize or certify
12 a nonemergency course of treatment for a patient within 2 working days after receipt of the
13 information necessary to make the determination;

14 (ii) make all determinations on whether to authorize or certify an
15 extended stay in a health care facility or additional health care services within 1 working
16 day after receipt of the information necessary to make the determination; and

17 (iii) promptly notify the health care provider of the determination.

18 (2) If within 3 calendar days after receipt of the initial request for health
19 care services the private review agent does not have sufficient information to make a
20 determination, the private review agent shall inform the health care provider that
21 additional information must be provided.

22 (3) If a private review agent requires prior authorization for an emergency
23 inpatient admission, or an admission for residential crisis services as defined in § 15-840
24 of this title, for the treatment of a mental, emotional, or substance abuse disorder, the
25 private review agent shall:

26 (i) make all determinations on whether to authorize or certify an
27 inpatient admission, or an admission for residential crisis services as defined in § 15-840
28 of this title, within 2 hours after receipt of the information necessary to make the
29 determination; and

30 (ii) promptly notify the health care provider of the determination.

31 **(4) FOR A STEP THERAPY EXCEPTION REQUEST SUBMITTED**
32 **ELECTRONICALLY IN ACCORDANCE WITH A PROCESS ESTABLISHED UNDER §**
33 **15-142(F) OF THIS TITLE OR A PRIOR AUTHORIZATION REQUEST SUBMITTED**

1 ELECTRONICALLY FOR PHARMACEUTICAL SERVICES, A PRIVATE REVIEW AGENT
2 SHALL MAKE A DETERMINATION:

3 (I) IN REAL TIME IF:

4 1. NO ADDITIONAL INFORMATION IS NEEDED BY THE
5 PRIVATE REVIEW AGENT TO PROCESS THE REQUEST; AND

6 2. THE REQUEST MEETS THE PRIVATE REVIEW AGENT’S
7 CRITERIA FOR APPROVAL; OR

8 (II) IF A REQUEST IS NOT APPROVED UNDER ITEM (I) OF THIS
9 PARAGRAPH, WITHIN 1 BUSINESS DAY AFTER THE PRIVATE REVIEW AGENT
10 RECEIVES ALL OF THE INFORMATION NECESSARY TO MAKE THE DETERMINATION.

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

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

Approved:

Governor.

Speaker of the House of Delegates.

President of the Senate.