Chapter 364

**(Senate Bill 515)**

AN ACT concerning

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

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

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

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

BY adding to
Article – Insurance
Section 15–854(g)
Annotated Code of Maryland
(2017 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 – Insurance**

15–142.

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

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

**(3) "STEP THERAPY EXCEPTION REQUEST" MEANS A REQUEST TO OVERRIDE A STEP THERAPY OR FAIL–FIRST PROTOCOL.**

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

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

**[**(4)**] (5)** "Supporting medical information" means:

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

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

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

(b) (1) This section applies to:

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

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

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

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

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

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

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

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

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

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

(2) otherwise required by law to be covered.

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

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

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

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

~~[~~(ii)~~]~~ ~~2.~~ supported by peer–reviewed medical literature~~; OR~~

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

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

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

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

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

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

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

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

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

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

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

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

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

~~(4) (I) A STEP THERAPY EXCEPTION REQUEST OR APPEAL SHALL BE GRANTED:~~

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

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

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

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

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

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

**(I) PREVENT:**

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

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

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

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

15–854.

(a) (1) This section applies to:

(i) insurers and nonprofit health service plans that provide coverage for prescription drugs through a pharmacy benefit 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 through a pharmacy benefit under individual or group contracts that are issued or delivered in the State.

(2) An insurer, a nonprofit health service plan, or a health maintenance organization that provides coverage for prescription drugs through a pharmacy benefits manager or that contracts with a private review agent under Subtitle 10B of this article 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.

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

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

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

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

15–10B–06.

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

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

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

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

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

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

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

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

**(4) FOR A STEP THERAPY EXCEPTION REQUEST SUBMITTED ELECTRONICALLY IN ACCORDANCE WITH A PROCESS ESTABLISHED UNDER § 15–142(F) OF THIS TITLE OR A PRIOR AUTHORIZATION REQUEST SUBMITTED ELECTRONICALLY FOR PHARMACEUTICAL SERVICES, A PRIVATE REVIEW AGENT SHALL MAKE A DETERMINATION:**

**(I) IN REAL TIME IF:**

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

**2. THE REQUEST MEETS THE PRIVATE REVIEW AGENT'S CRITERIA FOR APPROVAL; OR**

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

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, 2024.

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

**Approved by the Governor, May 3, 2023.**