SENATE BILL 111

J5, J4, J1 5lr1291

(PRE–FILED)

By: **Senator Lam**
Requested: October 21, 2024
Introduced and read first time: January 8, 2025
Assigned to: Finance

A BILL ENTITLED

AN ACT concerning

Maryland Medical Assistance Program and Health Insurance – Step Therapy, Fail–First Protocols, and Prior Authorization – Prescription to Treat Serious Mental Illness

FOR the purpose of prohibiting the Maryland Medical Assistance Program and certain insurers, nonprofit health service plans, health maintenance organizations, and managed care organizations from applying a prior authorization requirement, step therapy protocol, or fail–first protocol for prescription drugs used to treat certain mental illnesses of certain insureds and enrollees; and generally relating to coverage of prescription drugs to treat serious mental illness.

BY adding to
Article – Health – General
Section 15–102.3(m) and 15–157
Annotated Code of Maryland
(2023 Replacement Volume and 2024 Supplement)

BY repealing and reenacting, with amendments,
Article – Insurance
Section 15–142
Annotated Code of Maryland
(2017 Replacement Volume and 2024 Supplement)

BY adding to
Article – Insurance
Section 15–851.1
Annotated Code of Maryland
(2017 Replacement Volume and 2024 Supplement)

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

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

Article – Health – General

15–102.3.

(M) THE PROVISIONS OF §§ 15–142(E)(2) AND 15–851.1 OF THE INSURANCE ARTICLE APPLY TO MANAGED CARE ORGANIZATIONS.

15–157.

(A) IN THIS SECTION, "STEP THERAPY OR FAIL–FIRST PROTOCOL" HAS THE MEANING STATED IN § 15–142 OF THE INSURANCE ARTICLE.

(B) EXCEPT AS REQUIRED UNDER 42 U.S.C. § 1396A, BEGINNING JULY 1, 2025, THE PROGRAM MAY NOT APPLY A PRIOR AUTHORIZATION REQUIREMENT FOR A PRESCRIPTION DRUG USED TO TREAT AN ADULT ENROLLEE'S DIAGNOSIS OF:

(1) BIPOLAR DISORDER;

(2) SCHIZOPHRENIA;

(3) MAJOR DEPRESSION;

(4) POST–TRAUMATIC STRESS DISORDER; OR

(5) A MEDICATION–INDUCED MOVEMENT DISORDER ASSOCIATED WITH THE TREATMENT OF A SERIOUS MENTAL ILLNESS.

(C) BEGINNING JULY 1, 2025, THE PROGRAM MAY NOT APPLY A STEP THERAPY OR FAIL–FIRST PROTOCOL FOR A PRESCRIPTION DRUG USED TO TREAT AN ENROLLEE'S DIAGNOSIS OF:

(1) BIPOLAR DISORDER;

(2) SCHIZOPHRENIA;

(3) MAJOR DEPRESSION;

(4) POST–TRAUMATIC STRESS DISORDER; OR

(5) A MEDICATION–INDUCED MOVEMENT DISORDER ASSOCIATED WITH THE TREATMENT OF A SERIOUS MENTAL ILLNESS.

SECTION 2. AND BE IT FURTHER ENACTED, 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.

(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.

(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 DIAGNOSIS OF:

(I) BIPOLAR DISORDER;

(II) SCHIZOPHRENIA;

(III) MAJOR DEPRESSION;

(IV) POST–TRAUMATIC STRESS DISORDER; OR

(V) A MEDICATION–INDUCED MOVEMENT DISORDER ASSOCIATED WITH THE TREATMENT OF A SERIOUS MENTAL ILLNESS.

(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 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) 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:

(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

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.

15–851.1.

(A) (1) THIS SECTION APPLIES TO:

(I) INSURERS AND NONPROFIT HEALTH SERVICE PLANS THAT PROVIDE COVERAGE FOR PRESCRIPTION DRUGS 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 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 IS SUBJECT TO THE REQUIREMENTS OF THIS SECTION.

(B) EXCEPT AS REQUIRED UNDER 42 U.S.C. § 1396A, AN ENTITY SUBJECT TO THIS SECTION MAY NOT APPLY A PRIOR AUTHORIZATION REQUIREMENT FOR A PRESCRIPTION DRUG USED TO TREAT AN ADULT INSURED'S OR ENROLLEE'S DIAGNOSIS OF:

(1) BIPOLAR DISORDER;

(2) SCHIZOPHRENIA;

(3) MAJOR DEPRESSION;

(4) POST–TRAUMATIC STRESS DISORDER; OR

(5) A MEDICATION–INDUCED MOVEMENT DISORDER ASSOCIATED WITH THE TREATMENT OF A SERIOUS MENTAL ILLNESS.

SECTION 3. AND BE IT FURTHER ENACTED, That:

(a) On or before January 31, 2027, and each January 1 thereafter through 2031, the Maryland Department of Health shall report to the Department of Legislative Services on any cost increase to the Maryland Medical Assistance Program from the immediately preceding fiscal year that results from the implementation of Section 1 of this Act.

(b) On or before April 30 of the year in which a report is submitted under subsection (a) of this section, the Department of Legislative Services shall determine, based on the report, whether the implementation of Section 1 of this Act resulted in a cost increase to the Maryland Medical Assistance Program of more than $2,000,000 from the immediately preceding fiscal year.

(c) If the Department of Legislative Services determines that the implementation of Section 1 of this Act resulted in a cost increase to the Maryland Medical Assistance Program of more than $2,000,000 from the immediately preceding fiscal year, with no further action required by the General Assembly, at the end of April 30 of the year the determination is made, Section 1 of this Act shall be abrogated and of no further force and effect.

SECTION 4. AND BE IT FURTHER ENACTED, That Section 2 of this Act shall apply to all policies, contracts, and health benefit plans issued, delivered, or renewed in the State on or after January 1, 2026.

SECTION 5. AND BE IT FURTHER ENACTED, That Section 2 of this Act shall take effect January 1, 2026.

SECTION 6. AND BE IT FURTHER ENACTED, That, except as provided in Section 5 of this Act, this Act shall take effect July 1, 2025.