J5, J1, J4

4lr3118

CF 4lr3119

By: Senator Lam

Introduced and read first time: February 2, 2024

Assigned to: Finance

## A BILL ENTITLED

1	AN ACT concerning
2 3	Maryland Medical Assistance Program and Health Insurance – Step Therapy, Fail–First Protocols, and Prior Authorization – Prescription Drugs to Treat
4	Serious Mental Illness
5	FOR the purpose of prohibiting the Maryland Medical Assistance Program and certain
6	insurers, nonprofit health service plans, health maintenance organizations, and
7	managed care organizations from applying a prior authorization requirement, step
8	therapy protocol, or fail-first protocol for prescription drugs used to treat certain
9 10	mental illnesses; and generally relating to health insurance and coverage of prescription drugs to treat serious mental illness.
11	BY adding to
12	Article – Health – General
13	Section 15–102.3(m) and 15–155
14	Annotated Code of Maryland
15	(2023 Replacement Volume)
16	BY repealing and reenacting, with amendments,
<b>17</b>	Article – Insurance
18	Section 15–142
19	Annotated Code of Maryland
20	(2017 Replacement Volume and 2023 Supplement)
21	BY adding to
22	Article – Insurance
23	Section 15–851.1
24	Annotated Code of Maryland
25	(2017 Replacement Volume and 2023 Supplement)
26	SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND,

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

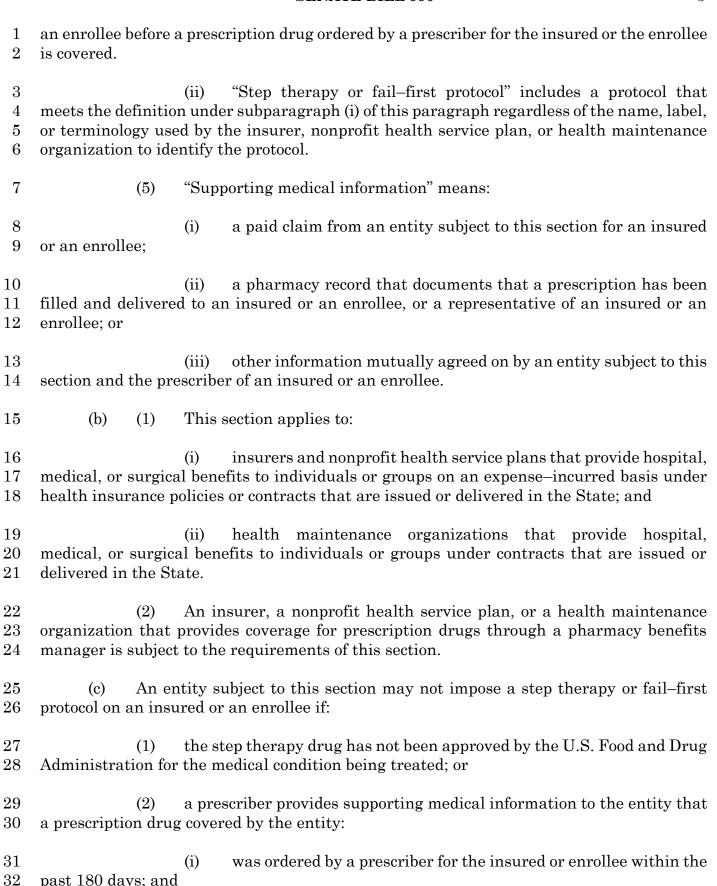
[Brackets] indicate matter deleted from existing law.

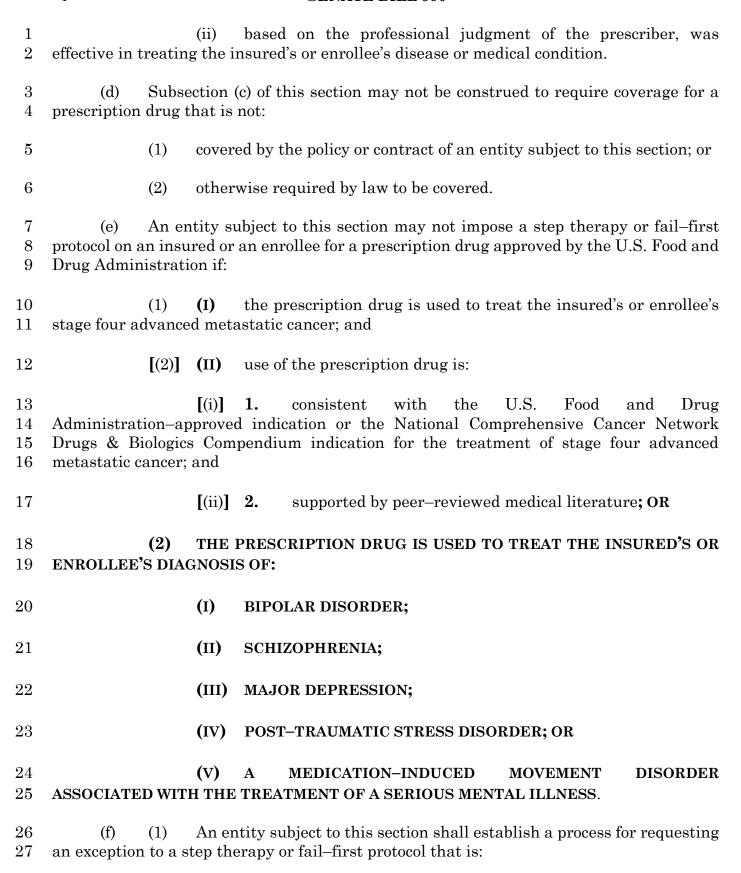
That the Laws of Maryland read as follows:

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## Article - Health - General 1 2 15-102.3.3 THE PROVISIONS OF §§ 15–142(E)(2) AND 15–851.1 OF THE INSURANCE 4 ARTICLE APPLY TO MANAGED CARE ORGANIZATIONS. 5 **15–155.** 6 BEGINNING JULY 1, 2024, THE PROGRAM MAY NOT APPLY A PRIOR AUTHORIZATION REQUIREMENT, FAIL-FIRST PROTOCOL, OR STEP THERAPY 8 PROTOCOL FOR A PRESCRIPTION DRUG USED TO TREAT AN ENROLLEE'S DIAGNOSIS 9 OF: 10 **(1)** BIPOLAR DISORDER; 11 **(2)** SCHIZOPHRENIA; 12 **(3)** MAJOR DEPRESSION; **(4)** 13 POST-TRAUMATIC STRESS DISORDER; OR 14 A MEDICATION-INDUCED MOVEMENT DISORDER ASSOCIATED **(5)** 15 WITH THE TREATMENT OF A SERIOUS MENTAL ILLNESS. 16 SECTION 2. AND BE IT FURTHER ENACTED, That the Laws of Maryland read as follows: 17 18 Article - Insurance 19 15-142.20 (a) (1) In this section the following words have the meanings indicated. 21"Step therapy drug" means a prescription drug or sequence of 22prescription drugs required to be used under a step therapy or fail-first protocol. 23 "Step therapy exception request" means a request to override a step (3)therapy or fail-first protocol. 2425"Step therapy or fail-first protocol" means a protocol established 26 by an insurer, a nonprofit health service plan, or a health maintenance organization that 27 requires a prescription drug or sequence of prescription drugs to be used by an insured or





1 2 3	(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;
4	(ii) easily accessible to the prescriber; and
5	(iii) posted on the entity's website.
6 7 8	(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:
9 10	(i) the step therapy drug is contraindicated or will likely cause an adverse reaction to the insured or enrollee;
11 12 13	(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;
14 15 16	(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
17 18	(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:
19 20	1. is in the same pharmacologic class or has the same mechanism of action as the step therapy drug; and
21 22	2. was discontinued by the prescriber due to lack of efficacy or effectiveness, diminished effect, or an adverse event.
23 24 25	(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.
26 27	(4) An enrollee or insured may appeal a step therapy exception request denial in accordance with Subtitle 10A or Subtitle 10B of this title.
28	(5) This subsection may not be construed to:
29	(i) prevent:
30 31 32	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

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- 1 a health care provider from prescribing a prescription 2 drug that is determined to be medically appropriate; or 3 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. 4 5 An entity subject to this section may use an existing step therapy exception process that satisfies the requirements under this subsection. 6 7 15-851.1. (A) (1) 8 THIS SECTION APPLIES TO: 9 (I)INSURERS AND NONPROFIT HEALTH SERVICE PLANS THAT 10 PROVIDE COVERAGE FOR PRESCRIPTION DRUGS UNDER INDIVIDUAL, GROUP, OR 11 BLANKET HEALTH INSURANCE POLICIES OR CONTRACTS THAT ARE ISSUED OR 12 DELIVERED IN THE STATE; AND 13 (II)HEALTH MAINTENANCE ORGANIZATIONS THAT PROVIDE 14 COVERAGE FOR PRESCRIPTION DRUGS UNDER INDIVIDUAL OR GROUP CONTRACTS 15 THAT ARE ISSUED OR DELIVERED IN THE STATE. 16 **(2)** AN INSURER, A NONPROFIT HEALTH SERVICE PLAN, OR A HEALTH MAINTENANCE ORGANIZATION THAT PROVIDES COVERAGE FOR PRESCRIPTION 17 18 DRUGS THROUGH A PHARMACY BENEFITS MANAGER IS SUBJECT TO THE 19 REQUIREMENTS OF THIS SECTION. 20 AN ENTITY SUBJECT TO THIS SECTION MAY NOT APPLY A PRIOR **(B)** 21AUTHORIZATION REQUIREMENT FOR A PRESCRIPTION DRUG USED TO TREAT THE INSURED'S OR ENROLLEE'S DIAGNOSIS OF: 22 23 **(1) BIPOLAR DISORDER**; **(2)** 24 **SCHIZOPHRENIA**; 25**(3) MAJOR DEPRESSION;** 26 **(4)** POST-TRAUMATIC STRESS DISORDER; OR 27 A MEDICATION-INDUCED MOVEMENT DISORDER ASSOCIATED **(5)** 
  - SECTION 3. AND BE IT FURTHER ENACTED, That:

WITH THE TREATMENT OF A SERIOUS MENTAL ILLNESS.

- 1 (a) On or before January 31, 2026, and each January 1 thereafter through 2030, 2 the Maryland Department of Health shall report to the Department of Legislative Services 3 on any cost increase to the Maryland Medical Assistance Program from the immediately 4 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.

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- 10 (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, 2025.
- SECTION 5. AND BE IT FURTHER ENACTED, That Section 2 of this Act shall take effect January 1, 2025.
- SECTION 6. AND BE IT FURTHER ENACTED, That, except as provided in Section 5 of this Act, this Act shall take effect July 1, 2024.