# HOUSE BILL 1087

J5, J4	5lr3160 CF SB 921
By: Delegates Bhandari <del>and Woods</del> , Woods, Alston, Bagnall, Chish	olm, Cullison,

<u>Guzzone, Hill, Hutchinson, S. Johnson, Kaiser, Kerr, Kipke, Lopez,</u> <u>Martinez, M. Morgan, Pena-Melnyk, Reilly, Rosenberg, Ross, Szeliga,</u> Taveras, White Holland, and Woorman

Introduced and read first time: February 5, 2025 Assigned to: Health and Government Operations

Committee Report: Favorable with amendments House action: Adopted Read second time: March 6, 2025

CHAPTER \_\_\_\_\_

## 1 AN ACT concerning

# Health Insurance – Step Therapy or Fail–First Protocols – Drugs to Treat Associated Conditions of Advanced Metastatic Cancer

- 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
  certain prescription drugs used prescribed by a treating physician to treat a
  symptom of or a side effect from treatment of certain metastatic cancer under certain
  circumstances; and generally relating to step therapy and fail-first protocols and
  health insurance.
- 10 BY repealing and reenacting, without amendments,
- 11 Article Insurance
- 12 Section 15–142(a)(1) and (4) and (b)
- 13 Annotated Code of Maryland
- 14 (2017 Replacement Volume and 2024 Supplement)
- 15 BY repealing and reenacting, with amendments,
- 16 Article Insurance
- 17 Section 15–142(e)
- 18 Annotated Code of Maryland
- 19 (2017 Replacement Volume and 2024 Supplement)

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.

<u>Underlining</u> indicates amendments to bill.

Strike out indicates matter stricken from the bill by amendment or deleted from the law by amendment.



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

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### Article – Insurance

- 4 15–142.
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(a) (1) In this section the following words have the meanings indicated.

6 (4) (i) "Step therapy or fail-first protocol" means a protocol established 7 by an insurer, a nonprofit health service plan, or a health maintenance organization that 8 requires a prescription drug or sequence of prescription drugs to be used by an insured or 9 an enrollee before a prescription drug ordered by a prescriber for the insured or the enrollee 10 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.

15 (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

19 (ii) health maintenance organizations that provide hospital, 20 medical, or surgical benefits to individuals or groups under contracts that are issued or 21 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.

(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

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

U.S. 31[(i)] 1. consistent with the Food and Drug Administration-approved indication or the National Comprehensive Cancer Network 3233 Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer: and 34

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1 [(ii)] **2**. supported by peer-reviewed medical literature; OR  $\mathbf{2}$ THE PRESCRIPTION DRUG IS USED PRESCRIBED BY A (2) **(I)** TREATING PHYSICIAN TO TREAT A SYMPTOM OF OR A SIDE EFFECT FROM 3 4 TREATMENT OF THE INSURED'S OR ENROLLEE'S STAGE FOUR ADVANCED METASTATIC CANCER THAT THE TREATING PROVIDER DETERMINES WILL  $\mathbf{5}$ **NEGATIVELY IMPACT THE INSURED'S OR ENROLLEE'S HEALTH IF-LEFT UNTREATED;** 6 7 AND 8 **(II) USE OF THE PRESCRIPTION DRUG IS:** 9 1. CONSISTENT WITH BEST PRACTICES FOR THE 10 TREATMENT OF STAGE FOUR ADVANCED METASTATIC CANCER, A CONDITION ASSOCIATED WITH STAGE FOUR ADVANCED METASTATIC CANCER, OR A SIDE EFFECT 11 12ASSOCIATED WITH STAGE FOUR ADVANCED METASTATIC CANCER TREATMENT; AND 2. 13 SUPPORTED BY PEER-REVIEWED **MEDICAL** 14LITERATURE; AND 15(III) THE PRESCRIPTION DRUG IS COVERED UNDER THE TERMS OF THE POLICY OR CONTRACT OF THE INSURED OR ENROLLEE. 16 17SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall apply to all 18 policies, contracts, and health benefit plans issued, delivered, or renewed in the State on or after January 1, 2026. 19 SECTION 3. AND BE IT FURTHER ENACTED, That this Act shall take effect 20 21January 1, 2026.

Approved:

Governor.

Speaker of the House of Delegates.

President of the Senate.

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