

# SENATE BILL 921

J5, J4

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CF HB 1087

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By: **Senator Gile**

Introduced and read first time: January 28, 2025

Assigned to: Finance

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Committee Report: Favorable with amendments

Senate action: Adopted

Read second time: March 10, 2025

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## CHAPTER \_\_\_\_\_

1 AN ACT concerning

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

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  
6 certain prescription drugs ~~used~~ prescribed by a treating physician to treat a  
7 symptom of or a side effect from treatment of certain metastatic cancer under certain  
8 circumstances; and generally relating to step therapy and fail–first protocols and  
9 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)

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

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**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.



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**Article – Insurance**

2 15–142.

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

4 (4) (i) “Step therapy or fail–first protocol” means a protocol established  
5 by an insurer, a nonprofit health service plan, or a health maintenance organization that  
6 requires a prescription drug or sequence of prescription drugs to be used by an insured or  
7 an enrollee before a prescription drug ordered by a prescriber for the insured or the enrollee  
8 is covered.9 (ii) “Step therapy or fail–first protocol” includes a protocol that  
10 meets the definition under subparagraph (i) of this paragraph regardless of the name, label,  
11 or terminology used by the insurer, nonprofit health service plan, or health maintenance  
12 organization to identify the protocol.

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

14 (i) insurers and nonprofit health service plans that provide hospital,  
15 medical, or surgical benefits to individuals or groups on an expense–incurred basis under  
16 health insurance policies or contracts that are issued or delivered in the State; and17 (ii) health maintenance organizations that provide hospital,  
18 medical, or surgical benefits to individuals or groups under contracts that are issued or  
19 delivered in the State.20 (2) An insurer, a nonprofit health service plan, or a health maintenance  
21 organization that provides coverage for prescription drugs through a pharmacy benefits  
22 manager is subject to the requirements of this section.23 (e) An entity subject to this section may not impose a step therapy or fail–first  
24 protocol on an insured or an enrollee for a prescription drug approved by the U.S. Food and  
25 Drug Administration if:26 (1) **(I)** the prescription drug is used to treat the insured’s or enrollee’s  
27 stage four advanced metastatic cancer; and28 **[(2)] (II)** use of the prescription drug is:29 **[(i)] 1.** consistent with the U.S. Food and Drug  
30 Administration–approved indication or the National Comprehensive Cancer Network  
31 Drugs & Biologics Compendium indication for the treatment of stage four advanced  
32 metastatic cancer; and33 **[(ii)] 2.** supported by peer–reviewed medical literature; **OR**

1                   **(2) (I) THE PRESCRIPTION DRUG IS ~~USED~~ PRESCRIBED BY A**  
 2 **TREATING PHYSICIAN TO TREAT A SYMPTOM OF OR A SIDE EFFECT FROM**  
 3 **TREATMENT OF THE INSURED’S OR ENROLLEE’S STAGE FOUR ADVANCED**  
 4 **METASTATIC CANCER ~~THAT THE TREATING PROVIDER DETERMINES WILL~~**  
 5 **~~NEGATIVELY IMPACT THE INSURED’S OR ENROLLEE’S HEALTH IF LEFT UNTREATED;~~**  
 6 **~~AND~~**

7                   **(II) USE OF THE PRESCRIPTION DRUG IS:**

8                   **1. CONSISTENT WITH BEST PRACTICES FOR THE**  
 9 **TREATMENT OF STAGE FOUR ADVANCED METASTATIC CANCER, A CONDITION**  
 10 **ASSOCIATED WITH STAGE FOUR ADVANCED METASTATIC CANCER, OR A SIDE EFFECT**  
 11 **ASSOCIATED WITH STAGE FOUR ADVANCED METASTATIC CANCER TREATMENT; AND**

12                   **2. SUPPORTED BY PEER-REVIEWED MEDICAL**  
 13 **LITERATURE; AND**

14                   **(III) THE PRESCRIPTION DRUG IS COVERED UNDER THE TERMS**  
 15 **OF THE POLICY OR CONTRACT OF THE INSURED OR ENROLLEE.**

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

19           SECTION 3. AND BE IT FURTHER ENACTED, That this Act shall take effect  
 20 January 1, 2026.

Approved:

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Governor.

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President of the Senate.

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Speaker of the House of Delegates.