

SENATE BILL 921

J5, J4

5lr3400
CF HB 1087

By: **Senator Gile**

Introduced and read first time: January 28, 2025

Assigned to: Finance

A BILL ENTITLED

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 to treat a symptom of or a side effect from treatment
7 of certain metastatic cancer under certain circumstances; and generally relating to
8 step therapy and fail–first protocols and health insurance.

9 BY repealing and reenacting, without amendments,
10 Article – Insurance
11 Section 15–142(a)(1) and (4) and (b)
12 Annotated Code of Maryland
13 (2017 Replacement Volume and 2024 Supplement)

14 BY repealing and reenacting, with amendments,
15 Article – Insurance
16 Section 15–142(e)
17 Annotated Code of Maryland
18 (2017 Replacement Volume and 2024 Supplement)

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

21 **Article – Insurance**

22 15–142.

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

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



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

6 (ii) “Step therapy or fail–first protocol” includes a protocol that
 7 meets the definition under subparagraph (i) of this paragraph regardless of the name, label,
 8 or terminology used by the insurer, nonprofit health service plan, or health maintenance
 9 organization to identify the protocol.

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

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

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

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

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

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

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

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

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

31 (2) (I) THE PRESCRIPTION DRUG IS USED TO TREAT A SYMPTOM OF
 32 OR A SIDE EFFECT FROM TREATMENT OF THE INSURED’S OR ENROLLEE’S STAGE
 33 FOUR ADVANCED METASTATIC CANCER THAT THE TREATING PROVIDER
 34 DETERMINES WILL NEGATIVELY IMPACT THE INSURED’S OR ENROLLEE’S HEALTH IF
 35 LEFT UNTREATED; AND

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

2 **1. CONSISTENT WITH BEST PRACTICES FOR THE**
3 **TREATMENT OF STAGE FOUR ADVANCED METASTATIC CANCER, A CONDITION**
4 **ASSOCIATED WITH STAGE FOUR ADVANCED METASTATIC CANCER, OR A SIDE EFFECT**
5 **ASSOCIATED WITH STAGE FOUR ADVANCED METASTATIC CANCER TREATMENT; AND**

6 **2. SUPPORTED BY PEER-REVIEWED MEDICAL**
7 **LITERATURE.**

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

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