

SENATE BILL 646

J5, J4

5lr2852
CF 5lr2851

By: **Senator Muse**

Introduced and read first time: January 25, 2025

Assigned to: Finance

A BILL ENTITLED

1 AN ACT concerning

2 **Health Insurance – Insulin – Prohibition on Step Therapy or Fail–First**
3 **Protocols**

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 insulin or certain other similar medications used to treat an insured’s or enrollee’s
7 diabetes; and generally relating to use of step therapy and fail–first protocols.

8 BY repealing and reenacting, without amendments,

9 Article – Insurance

10 Section 15–142(a)(1) and (4) and (b)

11 Annotated Code of Maryland

12 (2017 Replacement Volume and 2024 Supplement)

13 BY repealing and reenacting, with amendments,

14 Article – Insurance

15 Section 15–142(e)

16 Annotated Code of Maryland

17 (2017 Replacement Volume and 2024 Supplement)

18 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND,

19 That the Laws of Maryland read as follows:

20 **Article – Insurance**

21 15–142.

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

23 (4) (i) “Step therapy or fail–first protocol” means a protocol established
24 by an insurer, a nonprofit health service plan, or a health maintenance organization that

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 requires a prescription drug or sequence of prescription drugs to be used by an insured or
 2 an enrollee before a prescription drug ordered by a prescriber for the insured or the enrollee
 3 is covered.

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

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

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

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

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

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

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

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

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

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

29 (2) THE PRESCRIPTION DRUG IS:

30 (I) USED TO TREAT THE INSURED’S OR ENROLLEE’S TYPE 1,
 31 TYPE 2, OR GESTATIONAL DIABETES; AND

32 (II) 1. INSULIN; OR

1 **2. AN INSULIN ANALOG OR OTHER PRESCRIPTION DRUG**
2 **THAT PERFORMS A SIMILAR FUNCTION TO INSULIN, REGARDLESS OF THE**
3 **ACTIVATION PERIOD, WHETHER THE SOLUTION IS MIXED BEFORE OR AFTER**
4 **DISPENSING, OR WHETHER THE DRUG IS ADMINISTERED BY INJECTION OR**
5 **INHALATION.**

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

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