

SENATE BILL 646

J5, J4

5lr2852
CF HB 970

By: **Senator Muse**

Introduced and read first time: January 25, 2025

Assigned to: Finance

Committee Report: Favorable with amendments

Senate action: Adopted

Read second time: March 11, 2025

CHAPTER _____

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~~ or an insulin analog used to treat an
7 insured's or enrollee's diabetes; and generally relating to use of step therapy and
8 fail-first protocols.

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**

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.



1 15–142.

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

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

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

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

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

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

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

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

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

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

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

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

33 (2) THE PRESCRIPTION DRUG IS:

1 ~~(H)~~ INSULIN OR AN INSULIN ANALOG USED TO TREAT THE
2 INSURED’S OR ENROLLEE’S TYPE 1, TYPE 2, OR GESTATIONAL DIABETES; ~~AND~~

3 ~~(H)~~ 1. INSULIN; OR

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

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

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

Approved:

Governor.

President of the Senate.

Speaker of the House of Delegates.