

Chapter 689

(Senate Bill 646)

AN ACT concerning

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

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

BY repealing and reenacting, without amendments,

Article – Insurance

Section 15–142(a)(1) and (4) and (b)

Annotated Code of Maryland

(2017 Replacement Volume and 2024 Supplement)

BY repealing and reenacting, with amendments,

Article – Insurance

Section 15–142(e)

Annotated Code of Maryland

(2017 Replacement Volume and 2024 Supplement)

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

Article – Insurance

15–142.

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

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

(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

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

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

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

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

(2) THE PRESCRIPTION DRUG IS:

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

~~(II) 1. INSULIN; OR~~

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

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

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

Approved by the Governor, May 20, 2025.