

Department of Legislative Services
Maryland General Assembly
2025 Session

FISCAL AND POLICY NOTE
Third Reader - Revised

Senate Bill 646

(Senator Muse)

Finance

Health and Government Operations

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

This bill prohibits certain insurers, nonprofit health service plans, or health maintenance organizations (collectively known as carriers) from imposing a step therapy or fail-first protocol for insulin or an insulin analog that is approved by the U.S. Food and Drug Administration (FDA) and used to treat Type 1, Type 2, or gestational diabetes. **The bill takes effect January 1, 2026, and applies to all policies, contracts, and health benefit plans issued, delivered, or renewed in the State on or after that date.**

Fiscal Summary

State Effect: Minimal special fund revenue increase for the Maryland Insurance Administration (MIA) from the \$125 rate and form filing fee in FY 2026 only. Review of filings can likely be handled with existing MIA resources. No impact on the State Employee and Retiree Health and Welfare Benefits Program as the program does not have step therapy or fail-first protocols on insulin (or other medications) used to treat diabetes.

Local Effect: None.

Small Business Effect: Minimal.

Analysis

Current Law: Chapters 316 and 317 of 2014 established requirements for step therapy or fail-first protocols imposed by carriers, including carriers that provide coverage for prescription drugs through a pharmacy benefits manager (PBM). “Step therapy or fail-first protocol” means a protocol established by a carrier that requires a prescription drug or

sequence of prescription drugs to be used by an insured or enrollee before a prescription drug ordered by a prescriber is covered.

A step therapy or fail-first protocol may not be imposed if the step therapy drug has not been FDA-approved for the medical condition being treated or a prescriber provides supporting medical information to the carrier or PBM that a prescription drug covered by the carrier or PBM (1) was ordered for the insured or enrollee within the past 180 days and (2) based on the professional judgment of the prescriber, was effective in treating the insured or enrollee. These requirements for step therapy or fail-first protocols may not be construed to require coverage for a prescription drug that is not covered by the policy or contract or otherwise required to be covered by law.

A carrier may not impose a step therapy or fail-first protocol on an insured or enrollee for an FDA-approved prescription drug that is used to treat the insured's or enrollee's stage four advanced metastatic cancer if the use of the drug is supported by peer-reviewed medical literature and is consistent with the FDA-approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four metastatic cancer.

Additional Information

Recent Prior Introductions: Similar legislation has not been introduced in the last three years.

Designated Cross File: HB 970 (Delegate Woods, *et al.*) - Health and Government Operations.

Information Source(s): Department of Budget and Management; Maryland Insurance Administration; Department of Legislative Services

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