

Department of Legislative Services
Maryland General Assembly
2017 Session

FISCAL AND POLICY NOTE
Third Reader - Revised

Senate Bill 919

(Senator Mathias, *et al.*)

Finance

Health and Government Operations

President Jimmy Carter Cancer Treatment Access Act

This bill prohibits an insurer, nonprofit health service plan, or health maintenance organization (collectively known as carriers) from imposing a step therapy or fail-first protocol on an insured or enrollee for a prescription drug approved by the U.S. Food and Drug Administration (FDA) under specified circumstances. First, the drug must be used to treat the insured's or enrollee's stage four advanced metastatic cancer. Second, use of the drug must be consistent with the FDA-approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four metastatic cancer. Finally, use of the drug must also be supported by peer-reviewed medical literature.

The bill applies to all policies, contracts, and health benefit plans issued, delivered, or renewed in the State on or after October 1, 2017.

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 2018. Review of filings can likely be handled with existing MIA resources. No effect on the State Employee and Retiree Health and Welfare Benefits Program as it does not require step therapy or fail-first protocols for oncology drugs.

Local Effect: Any impact on local governments with fully insured health benefit plans is assumed to be minimal.

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 approved by FDA for the medical condition being treated (*i.e.*, off-label use) 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 requirement 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.

Chapters 316 and 317 also required the Maryland Health Care Commission (MHCC) to work with payors and providers to attain benchmarks for overriding a payor’s step therapy or fail-first protocol. By July 1, 2015, each payor that requires a step therapy or fail-first protocol had to establish a process for a provider to override the protocol. According to MHCC, all payors and PBMs that require a step therapy or fail-first protocol have implemented such a process. Links to each payor’s and PBM’s process are available on the MHCC [website](#).

Background: According to the National Cancer Institute, cancer cells can spread (1) locally by moving into nearby normal tissue; (2) regionally by moving to nearby lymph nodes, tissues, or organs; or (3) to distant parts of the body. When cancer spreads to distant parts of the body, it is called metastatic cancer. For many types of cancer, it is also called stage four cancer. Although some types of metastatic cancer can be cured with current treatments, most cannot. Even so, there are treatments for metastatic cancer. The goal of these treatments is to stop or slow the growth of the cancer or to relieve symptoms caused by it. In some cases, treatments for metastatic cancer may help prolong life.

Georgia’s 2016 *The Honorable Jimmy Carter Cancer Treatment Access Act* prohibits any health benefit plan in the state that directly or indirectly covers the treatment of stage four advanced, metastatic cancer from limiting or excluding coverage for an FDA-approved drug by requiring that the insured first fail to successfully respond to a different drug or drugs or prove a history of failure of such drug or drugs, provided that the use of such drug or drugs is consistent with best practices for the treatment of stage four advanced, metastatic cancer and is supported by peer-reviewed medical literature.

Additional Information

Prior Introductions: None.

Cross File: HB 740 (Delegate Angel, *et al.*) - Health and Government Operations.

Information Source(s): National Cancer Institute; Department of Budget and Management; Department of Health and Mental Hygiene; Maryland Insurance Administration; Department of Legislative Services

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