

Department of Legislative Services
Maryland General Assembly
2009 Session

FISCAL AND POLICY NOTE
Revised

Senate Bill 985

(Senator Garagiola)

Finance

Health and Government Operations

**Health Insurance - Coverage for Off-Label Use of Drugs - Standard Reference
Compendia**

This bill alters the definition of “standard reference compendia” for purposes of mandated coverage of off-label use of drugs to mean any authoritative compendia as recognized periodically by the federal Secretary of Health and Human Services or the Maryland Insurance Commissioner.

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 2010. The review of rate filings and any resulting complaints can be handled within existing MIA resources. No impact on the State Employee and Retiree Health and Welfare Benefits Program (State plan).

Local Effect: None.

Small Business Effect: None. The bill does not apply to the small group health insurance market.

Analysis

Current Law: There are 43 mandated health insurance benefits that certain carriers must provide to their enrollees. If a policy or contract provides coverage for drugs, coverage must be provided for an off-label use of the drug if the drug is recognized for treatment in any of the standard reference compendia or in the medical literature. Coverage of an off-label use of a drug must include medically necessary services

associated with the administration of the drug. The mandate does not require coverage of a drug if the federal Food and Drug Administration (FDA) has determined use of the drug to be contraindicated or if the drug is experimental and not approved for any indication.

Every four years, the Maryland Health Care Commission (MHCC) examines the fiscal impact of mandated health insurance benefits. In January 2008, MHCC found that these benefits account for 15.4% of total premium costs for group health insurance and 18.6% of total premium costs for individual policies. The full cost of current mandated coverage for off-label use of drugs is reported at 0.2% of premium costs. Approximately 50% of self-funded health benefit plans voluntarily provide coverage for off-label use of drugs.

Background: Off-label use of a drug is the prescription of a medication in a manner different from that approved by the FDA. As many as one of every five drugs prescribed in the United States may be for off-label use. Off-label use is particularly prevalent in cancer therapy, where as many as 50% to 75% of all drug uses are off-label.

Due to changes in the pharmaceutical reference industry, fewer of the statutorily named compendia are available for reference. Both the United States Pharmacopeia Drug Information and the American Medical Association Drug Evaluations are no longer published. In October 2008, the U.S. Department of Health and Human Services (HHS) revised its list of recognized compendia for use in determination of a medically accepted indication of drugs and biologicals that are used off-label in an anti-cancer chemotherapeutic regimen. The bill alters Maryland law to reflect those compendia recognized by HHS.

Additional Information

Prior Introductions: None.

Cross File: HB 456 (Delegate Morhaim) - Health and Government Operations.

Information Source(s): Randall S. Stafford, "Regulating Off-Label Drug Use – Rethinking the Role of the FDA," *New England Journal of Medicine*, April 3, 2008; *Study of Mandated Health Insurance Services: A Comparative Evaluation*, Maryland Health Care Commission, January 1, 2008; National Comprehensive Cancer Network; U.S. Department of Health and Human Services; Department of Budget and Management; Department of Health and Mental Hygiene; Maryland Insurance Administration; Department of Legislative Services

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