

**Department of Legislative Services**  
 Maryland General Assembly  
 2013 Session

**FISCAL AND POLICY NOTE**

House Bill 1015 (Delegates Bromwell and Kach)  
 Health and Government Operations

**Health Insurance - Step Therapy or Fail-First Protocol**

This bill establishes requirements for step therapy or fail-first protocols imposed by health insurers, nonprofit health service plans, and health maintenance organizations (collectively known as carriers) that provide coverage for prescription drugs and devices, including carriers that use a pharmacy benefits manager (PBM).

The Maryland Health Care Commission (MHCC), in consultation with the Maryland Insurance Administration (MIA), must study the use of measures similar to a step therapy or fail-first protocol by health insurance carriers in their coverage of diagnostic imaging and medical and surgical procedures and report to specified committees of the General Assembly by January 1, 2014.

**Fiscal Summary**

**State Effect:** Special fund expenditures increase by \$50,000 in FY 2014 for MHCC to conduct the required study. The bill does not apply to the State Employee and Retiree Health and Welfare Benefits Program or the Medicaid program. No effect on revenues.

| (in dollars)   | FY 2014    | FY 2015 | FY 2016 | FY 2017 | FY 2018 |
|----------------|------------|---------|---------|---------|---------|
| Revenues       | \$0        | \$0     | \$0     | \$0     | \$0     |
| SF Expenditure | 50,000     | 0       | 0       | 0       | 0       |
| Net Effect     | (\$50,000) | \$0     | \$0     | \$0     | \$0     |

*Note:() = decrease; GF = general funds; FF = federal funds; SF = special funds; - = indeterminate effect*

**Local Effect:** None.

**Small Business Effect:** Potential minimal.

## Analysis

**Bill Summary:** “Step therapy or fail-first protocol” means a protocol that establishes a specific sequence in which (1) prescription drugs or devices that are medically appropriate for a specified medical condition and a particular patient are to be prescribed and (2) a preferred prescription drug or device is prescribed in the sequence.

The duration of a step therapy or fail-first protocol may not exceed the earlier of 30 days or the period deemed necessary by the prescriber to determine the clinical effectiveness of the prescription drug or device preferred by the carrier.

A carrier must allow a prescriber of a covered prescription drug or device to have immediate access to a clear and convenient process to override the step therapy or fail-first protocol. The override process must allow a prescriber to override the step therapy or fail-first protocol if, in the professional judgment of the prescriber (1) the prescription drug or device preferred by the carrier has been ineffective or (2) based on sound clinical, medical, and scientific evidence, the known relevant physical or mental characteristics of the patient, and the known characteristics of the treatment regimen, the prescription drug or device preferred by the carrier is likely *either* to be ineffective or adversely affect the compliance with the treatment regimen *or* has caused or is likely to cause an adverse reaction or other harm to the patient.

The bill may not be construed to require coverage for a condition that is not already covered by a carrier or otherwise required to be covered by law.

**Current Law:** PBMs are businesses that administer and manage prescription drug benefit plans for purchasers. PBMs must register with MIA prior to providing pharmacy benefits management services. The Insurance Commissioner is authorized to examine the affairs, transactions, accounts, and records of a registered PBM at the PBM’s expense. PBMs are prohibited from shipping, mailing, or delivering prescription drugs or devices to a person in the State through a nonresident pharmacy unless the nonresident pharmacy holds a nonresident pharmacy permit from the State Board of Pharmacy.

Each PBM must have a pharmacy and therapeutics committee and ensure that the committee has, among other things, a process to evaluate medical and scientific evidence concerning the safety and effectiveness of prescription drugs when recommending utilization review requirements, dose restrictions, and step therapy requirements.

A carrier that limits coverage of prescription drugs or devices to those in a formulary must establish and implement a procedure by which a member may receive a prescription drug or device that is not in the carrier’s formulary if, in the judgment of the authorized prescriber, (1) there is no equivalent prescription drug or device in the carrier’s formulary or (2) an equivalent prescription drug or device in the formulary *either* has been

ineffective in treating the disease or condition of the member *or* has caused or is likely to cause an adverse reaction or other harm to the member.

**Background:** Most major purchasers of prescription drugs, including commercial insurers, the PBMs with which they contract, Medicare Part D plans, and State Medicaid programs, utilize step therapy or fail-first protocols for cost-containment purposes. Step therapy or fail-first protocols shift patients to alternative prescription drugs, requiring an individual to try a preferred drug (usually a less costly generic) before progressing to a new drug based on the failure of the former medication to provide symptomatic relief or cure.

According to the National Conference of State Legislatures, Louisiana adopted legislation in 2011 that requires step therapy or fail-first protocols. Similar legislation is currently pending before the New York State Senate and Assembly.

Health care providers and patient advocates have expressed concern about step therapy or fail-first protocols as they interfere with a physician's ability to select the most appropriate prescription drug therapy and can increase the incidence of adverse reactions, unnecessarily subject patients to other harm, and lead to delays in treatment.

**State Expenditures:** Special fund expenditures increase by \$50,000 for MHCC in fiscal 2014. The bill requires MHCC, in consultation with MIA, to study the use of measures similar to step therapy or fail-first protocol by health insurance carriers in their coverage of diagnostic imaging and medical and surgical procedures. MHCC indicates that it will need to hire a consultant to complete this study and report on its findings by January 1, 2014.

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### Additional Information

**Prior Introductions:** None.

**Cross File:** SB 746 (Senator Middleton) - Finance.

**Information Source(s):** National Conference of State Legislatures, Department of Budget and Management, Department of Health and Mental Hygiene, Maryland Insurance Administration, Department of Legislative Services

**Fiscal Note History:** First Reader - February 19, 2013  
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