HB 1233

Department of Legislative Services

Maryland General Assembly
2014 Session

FISCAL AND POLICY NOTE
Revised

House Bill 1233 (Delegate Bromwell, *et al.*)
Health and Government Operations Finance

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), including carriers that provide coverage for prescription drugs through a pharmacy benefits manager (PBM). The Maryland Health Care Commission (MHCC) must 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 must establish a process for a provider to override the protocol. The bill also repeals obsolete reporting requirements regarding the status of obtaining other benchmarks.

The bill takes effect July 1, 2014.

Fiscal Summary

State Effect: Expenditures for the State Employee and Retiree Health and Welfare Benefits Program (State plan) increase by at least $75,000 and as much as $100,000 beginning in FY 2015 due to reduced savings in the prescription drug program. Special fund expenditures for MHCC increase by an estimated $25,000 in FY 2015 and 2016 only. Minimal special fund revenue increase for the Maryland Insurance Administration (MIA) from the $125 rate and form filing fee in FY 2015. Review of filings can be handled with existing MIA budgeted resources.

(in dollars)	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019
SF Revenue	-	$0	$0	$0	$0
GF Expenditure	$44,300	$44,300	$44,300	$44,300	$44,300
SF Expenditure	$47,500	$47,500	$22,500	$22,500	$22,500
FF Expenditure	$8,300	$8,300	$8,300	$8,300	$8,300
Net Effect	($100,000)	($100,000)	($75,000)	($75,000)	($75,000)

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

Local Effect: Local government expenditures for prescription drug coverage may increase.

Small Business Effect: Potential meaningful. Small businesses expenditures for prescription drug coverage may increase.

Analysis

Bill Summary: "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. "Supporting medical information" means a paid claim from a carrier or PBM, a pharmacy record that documents that a prescription has been filled and delivered, or other information mutually agreed on by a carrier or PBM and a prescriber.

A step therapy or fail-first protocol *may not* be imposed if the step therapy drug *has not* been approved by the U.S. Food and Drug Administration 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.

The bill 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.

Current Law: PBMs are businesses that administer and manage prescription drug benefit plans for purchasers. 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.

Chapters 534 and 535 of 2012 require MHCC to work with specified health care payors and providers to attain benchmarks for standardizing and automating the process required

by payors for preauthorizing health care services. The Acts establish dates by which benchmarks must be met, require MHCC to establish a process for waiving a payor or provider from the benchmarks for extenuating circumstances, and establish multiple reporting requirements. Benchmarks must include (1) by October 1, 2012 (Phase 1), establishment of online access for providers to each payor's list of health care services that require preauthorization and key criteria for making a determination on a preauthorization request; (2) by March 1, 2013 (Phase 2), establishment by each payor of an online process for accepting electronically a preauthorization request from a provider and assigning to a preauthorization request a unique electronic identification number that a provider may use to track the request; (3) by July 1, 2013 (Phase 3), establishment by each payor of an online preauthorization system to approve specified requests within specified timeframes; and (4) by July 1, 2015, utilization by providers of either the online preauthorization system or, if a national transaction standard has been established and adopted by the health care industry, as determined by MHCC, the provider's practice management, electronic health record, or e-prescribing system.

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.

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. According to the Maryland State Medical Society, three states (Connecticut, Louisiana, and New York) have adopted legislation governing step therapy or fail-first protocols.

At the request of legislative leadership, MHCC submitted a report to the General Assembly in January 2014 with recommendations for resolving the dispute between health insurance carriers and health care providers over step therapy. The report recommended three first steps in reconciling differences:

- Standardize step therapy, grandfathering exemptions to permit patients already successfully managed by a drug or service to continue with that treatment without having to restart step therapy protocols. MHCC recommends that all payors use a one-year look-back period (they currently vary from 130 to 365 days with exceptions based on the treating physician's documentation).

- Require all payors to incorporate step therapy approval and override processes in their automated preauthorization applications beginning in July 2015.
- Require all payors, including PBMs, to submit claim information to MHCC. Proposed and emergency regulations to implement this action are now moving through the regulatory process.

State Expenditures: State plan expenditures increase by at least $75,000 and as much as $100,000 beginning in fiscal 2015. This estimate represents a reduction in savings for prescription drug utilization management and cost containment. According to the Department of Budget and Management, expenditures for the State plan's current step therapy program increase as a result of the expanded look-back period for previous therapy. The bill increases the State plan's current 130-day period to 180 days.

While future year State plan expenditures are anticipated to continue to increase due to reduced savings, they cannot be reliably estimated at this time. State plan expenditures are split approximately 59% general funds, 30% special funds, and 11% federal funds.

Special fund expenditures for MHCC increase by $25,000 in fiscal 2015 to hire a vendor to collaborate with payors to develop specifications and conduct testing of override processes. In fiscal 2016, special fund expenditures again increase by $25,000 for the vendor to validate and audit the override processes.

Additional Information

Prior Introductions: None.

Cross File: SB 622 (Senator Middleton) - Finance.

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

Fiscal Note History: First Reader - February 18, 2014
ncs/ljm Revised - House Third Reader - March 25, 2014

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