HB 1359

Department of Legislative Services

Maryland General Assembly
2020 Session

FISCAL AND POLICY NOTE
First Reader

House Bill 1359 (Delegate P. Young, *et al.*)
Health and Government Operations

Health Insurance - Requirements for Establishing Step Therapy Protocol and Requesting Exceptions

This bill repeals current prohibitions against insurers, nonprofit health service plans, and health maintenance organizations (collectively known as carriers) imposing step therapy or fail-first protocols. Instead, a carrier, including a "utilization review organization," must establish a "step therapy protocol" by using clinical review criteria based on clinical practice guidelines, as specified. Carriers and utilization review organizations must establish a process for requesting an exception to a step therapy protocol that is clearly described, easily accessible by a patient and prescribing provider, and posted on the carrier's website. The Insurance Commissioner must adopt regulations to implement the bill. **The bill takes effect January 1, 2021, 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 increase in special fund revenues for the Maryland Insurance Administration from the $125 rate and form filing fee in FY 2021. Review of additional filings necessitates contractual support in FY 2021 only. Indeterminate but potentially significant impact on the State Employee and Retiree Health and Welfare Benefits Program, as discussed below.

Local Effect: The bill is not anticipated to materially affect local government operations or finances.

Small Business Effect: Minimal.

Analysis

Bill Summary: "Step therapy protocol" means a protocol, policy, or program that establishes a specific sequence in which prescription drugs must be used or tried for a specified medical condition and, as medically appropriate for a particular patient, to be covered by a carrier.

"Utilization review organization" means an entity that conducts utilization review, other than a carrier performing utilization review for its own health benefit plans. A pharmacy benefits manager (PBM) is a utilization review organization.

Clinical practice guidelines used to establish clinical review criteria for step therapy protocols must (1) recommend that specified prescription drugs be taken in the specific sequence required by the step therapy protocol; (2) be developed and endorsed by a multidisciplinary panel of experts that undertakes specified actions; (3) be based on high-quality studies, research, and medical practice; (4) be created by an explicit and transparent process; (5) take into account the needs of atypical patient populations and diagnoses; and (6) be continually updated through a review of new evidence, research, and newly developed treatments. In the absence of such clinical guidelines, peer-reviewed publications may be substituted.

A step therapy exception request must be expeditiously granted if (1) the required prescription drug is contraindicated or will likely cause an adverse reaction by or physical or mental harm to the patient; (2) the required prescription drug is expected to be ineffective based on the known clinical characteristics; (3) the patient has tried the required prescription drug or another prescription drug in the same pharmacologic class or with the same mechanism of action and use of that drug was discontinued for specified reasons; (4) the required prescription drug is not in the best interest of the patient, based on medical necessity; or (5) the patient is stable on a prescription drug selected by the patient's health care provider for the medical condition under consideration while the patient was covered by a current or previous health benefit plan with a current or previous insurer. If a step therapy exception request is granted, a carrier must authorize coverage for the prescription drug prescribed.

A carrier must grant or deny a step therapy exception request or an appeal within 72 hours after receiving the request or appeal or, in cases where exigent circumstances exist, within 24 hours. If a carrier does not grant or deny a step therapy exception request or an appeal within the required time period, the request or appeal must be treated as granted. Any step therapy exception request denied is eligible for appeal by an insured.

The bill may not be construed to prevent a carrier from requiring a patient to try an AB-rated generic equivalent or interchangeable biological product before providing

coverage for the equivalent branded prescription drug or requiring a pharmacist to make substitutions of prescription drugs consistent with State insurance law, or preventing a health care provider from prescribing a prescription drug that is determined to be medically appropriate.

Current Law: Under § 15-142 of the Insurance Article, "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 carrier may not impose a step therapy or fail-first protocol 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.

A carrier is also prohibited from imposing a step therapy or fail-first protocol if the prescription drug is used to treat the insured's or enrollee's stage four advanced metastatic cancer and use of the prescription drug is consistent with specified indications and supported by peer-reviewed medical literature.

State Expenditures: The State Employee and Retiree Health and Welfare Benefits Program is largely self-insured for its medical contracts and, as such, with the exception of the one fully insured integrated health model medical plan (Kaiser), does not fall under the definition of carrier under the bill. However, the program provides prescription drug coverage through a PBM, which is subject to the bill's requirements. The Department of Budget and Management (DBM) advises that the bill would reduce the department's ability to manage prescription drug utilization and, in turn, could increase expenditures by an indeterminate but potentially significant amount. DBM notes that an appeals process for requesting an exception regarding a step therapy protocol is already in place for the program.

Additional Information

Prior Introductions: None.

Designated Cross File: SB 952 (Senator Benson) - Finance.

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

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