Department of Legislative Services

Maryland General Assembly
2019 Session

FISCAL AND POLICY NOTE
First Reader

Senate Bill 405 (Senator Hayes, *et al.*)
Finance

Health Insurance - Prescription Drugs - Formulary Changes

This bill prohibits certain insurers, nonprofit health service plans, and health maintenance organizations (collectively known as carriers), during a plan year and the preceding open enrollment period, from (1) removing a prescription drug from a formulary; (2) if a generic equivalent is not available, moving a prescription drug to a benefit tier that requires a higher deductible, copayment, or coinsurance; or (3) adding a "utilization management restriction" to a prescription drug in the formulary. Specified exceptions are established. **The bill applies to all policies, contracts, and health benefit plans issued, delivered, or renewed in the State on or after January 1, 2020.**

Fiscal Summary

State Effect: The bill does not materially affect State finances. No impact on the State Employee and Retiree Health and Welfare Benefits Program (State Plan), as discussed below.

Local Effect: Potential increase in health care expenditures for local governments that purchase fully insured health benefit plans. Revenues are not affected.

Small Business Effect: Minimal.

Analysis

Bill Summary: "Utilization management restriction" means a restriction on coverage for a prescription drug on a formulary, including imposing or altering a quantity limit, adding a prior authorization requirement, and imposing a step therapy protocol restriction.

A carrier may remove a prescription drug from a formulary or impose a utilization management restriction if, at any time, (1) the U.S. Food and Drug Administration (FDA) calls into question the clinical safety of the drug; (2) the manufacturer has notified FDA of a discontinuation or interruption in manufacturing; or (3) the prescription drug is approved by FDA for use without a prescription.

The bill does not prohibit a carrier from adding a prescription to a formulary at any time or modifying a formulary at the time of renewal and before the open enrollment period. To modify a formulary, a carrier must, no later than 60 days before the modification is effective, provide written notice to the affected member and the affected member's authorized prescriber and post the modification on the carrier's online formulary.

Current Law: Under § 15-831 of the Insurance Article, each carrier that uses a prescription drug formulary must provide coverage for an off-formulary drug or device if, in the judgment of the authorized prescriber, (1) there is no equivalent drug or device in the formulary or (2) an equivalent drug or device in the formulary has been ineffective or has caused or is likely to cause an adverse reaction or other harm. A decision of a carrier not to provide access to or coverage of a prescription drug or device in accordance with these requirements constitutes an adverse decision if the decision is based on a finding that the proposed drug or device is not medically necessary, appropriate, or efficient.

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 impost a step therapy or fail-first protocol 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 pharmacy benefits manager (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.

State Expenditures: The State Plan 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), is not subject to this requirement. However, the State Plan generally provides coverage for mandated health insurance benefits. The Department of Budget and Management advises that the PBM contract for the State Plan's prescription plan currently permits formulary changes to occur only on the first day of each plan year (currently January 1). The contract requires a 45-day advance notice to affected participants. Extending this notice to 60 days can be handled with existing resources.

Additional Information

Prior Introductions: Legislation including similar provisions has been considered in recent legislative sessions. HB 1128 of 2017 was withdrawn. Its cross file, SB 768, received a hearing in the Senate Finance Committee but was withdrawn. HB 990 of 2015 received a hearing in the House Health and Government Operations Committee but was withdrawn. Its cross file, SB 834, received a hearing in the Senate Finance Committee, but no further action was taken.

Cross File: HB 435 (Delegate Kelly, *et al.*) - Health and Government Operations.

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

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