This bill establishes requirements for and prohibitions regarding utilization review for coverage of prescription drugs and devices by an insurer, nonprofit health service plan, or health maintenance organization (collectively known as carriers). The requirements and prohibitions apply to a carrier that provides coverage for prescription drugs and devices (including through a prescription drug benefits manager). The bill does not apply to a Medicaid managed care organization. **The bill takes effect January 1, 2023, 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; review of any filings can be handled with existing budgeted resources. Administrative costs for the State Employee and Retiree Health and Welfare Benefits Program may increase by an indeterminate amount beginning in FY 2023, as discussed below.

**Local Effect:** Potential increase in health insurance costs for local governments that purchase fully insured health plans. Revenues are not affected.

**Small Business Effect:** Potential increase in health insurance costs for small businesses with nongrandfathered small employer plans.
Analysis

Bill Summary:

Denial of Coverage

A denial of coverage for a prescription drug or device made during utilization review by a carrier must be made by a physician (1) who is in the same specialty as the prescriber of the drug or device subject to utilization review or (2) whose specialty focuses on the diagnosis and treatment of the condition for which the drug or device was provided to treat.

A carrier is not required to involve a physician in the utilization review of a prescription drug or device if the review does not result in the denial of coverage.

Expeditied Appeals

A denial of coverage for a prescription drug or device made during utilization review must be eligible for an expedited appeal if, in the professional judgment of the prescriber, the insured or enrollee will suffer serious harm without access to the drug or device.

On initiation of the expedited appeal by the prescriber, a carrier must render a decision on the expedited appeal within 48 hours. If a carrier does not render a decision within 48 hours, the initial denial of coverage must be automatically overturned and the insured or enrollee must be granted immediate approval for coverage of the prescription drug or device.

The decision rendered during the expedited appeal must be made by a physician (1) who is in the same specialty as the prescriber or (2) whose specialty focuses on the diagnosis and treatment of the condition for which the prescription drug or device was provided. The expedited appeal decision may not be made by the same physician who rendered the initial denial of coverage. The expedited appeal process must be independent and distinct from the carrier’s existing internal appeals process for coverage decisions or internal grievance process for adverse decisions or grievances.

Prohibitions on Utilization Review for Specified Drugs and Devices

A carrier may not perform utilization review on prescription drugs under the following circumstances:

- for generic prescription drugs that are not controlled dangerous substances (CDS);
- for any prescription drug, generic or brand name, that is not a CDS, after an insured or enrollee has been prescribed the drug without interruption for six months;
for any prescription drug or drugs, generic or brand name, on the ground of therapeutic duplication if the insured or enrollee has already been subject to utilization review on the ground of therapeutic duplication for the same dosage of the prescription drug or drugs and coverage of the prescription drug or drugs was approved; and

for any prescription drug, generic or brand name, solely because the dosage of the medication for the insured or enrollee has been adjusted by the prescriber.

**Current Law:** Under § 15-142 of the Insurance Article, 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 a 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. 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.

Title 15, Subtitle 10A of the Insurance Article requires a carrier to establish an internal grievance process, including an expedited process for use in an emergency case. Members may file a complaint with the Insurance Commissioner within four months after the receipt of an adverse decision or grievance decision from a carrier. The Commissioner must make final decisions on complaints. Carriers must submit quarterly reports with the Commissioner regarding appeals and grievances filed with the carrier.

Subtitle 10D of the Insurance Article requires carriers to establish an internal appeals process for coverage decisions. Decisions of the carrier may be appealed to the Commissioner. The Commissioner must make final decisions on coverage decisions.

**State Fiscal Effect:** The State Employee and Retiree Health and Welfare Benefits Program is largely self-insured for its medical contracts and, as such, except for the one fully insured integrated health model medical plan (Kaiser), is not subject to this bill. However, the program generally provides coverage as required under State law. The Department of Budget and Management advises that the bill’s requirements regarding which physicians can make a denial of coverage decision and a decision upon appeal have an operational impact on the program and likely increase administrative costs by an indeterminate amount beginning in fiscal 2023.
Additional Information

Prior Introductions: None.

Designated Cross File: None.

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

Fiscal Note History: First Reader - February 20, 2022

km/ljm

Analysis by: Jennifer B. Chasse

Direct Inquiries to:
(410) 946-5510
(301) 970-5510