HB 785

Department of Legislative Services

Maryland General Assembly
2023 Session

FISCAL AND POLICY NOTE
Third Reader - Revised

House Bill 785 (Delegate S. Johnson, *et al.*)
Health and Government Operations Finance

Health Insurance - Step Therapy or Fail-First Protocol and Prior Authorization - Revisions

This bill requires an insurer, nonprofit health service plan, and health maintenance organization (collectively known as carriers), including those that provide prescription drug coverage through a pharmacy benefits manager (PBM), to establish a process for requesting an exception to "a step therapy or fail-first protocol" that is clearly described, easily accessible to the prescriber, and posted on the carrier's or PBM's website. A "step therapy exception request" must be granted under specified circumstances, and an insured or enrollee may appeal the denial of a "step therapy exception request." A carrier or PBM may use an existing step therapy exception process that satisfies the requirements of the bill. A private review agent must make a determination regarding a step therapy exception or prior authorization request submitted electronically within a specified timeframe. A carrier or PBM may not require more than one prior authorization of the same prescription drug (except for certain opioids) under specified circumstances. **The bill takes effect January 1, 2024, 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 in FY 2024 only from the $125 rate and form filing fee; review of form filings can be handled with existing budgeted resources. 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 exception request" means a request to override a step therapy or fail-first protocol. "Step therapy or fail-first protocol" includes a protocol that meets the statutory definition, regardless of the name, label, or terminology used by the carrier to identify the protocol.

Approval of Step Therapy Exception Requests

A step therapy exception request must be granted if, based on the professional judgment of the prescriber and any required information and documentation required to be submitted with the request to be considered a complete request, (1) the step therapy drug is contraindicated or will likely cause an adverse reaction to the insured or enrollee; (2) the step therapy drug is expected to be ineffective based on the known clinical characteristics of the insured or enrollee and the known characteristics of the prescription drug regimen; (3) the insured or enrollee is stable on a prescription drug for the medical condition under consideration under the current or a previous source of coverage; or (4) the insured or enrollee, while covered by a current or previous source of coverage, has tried a prescription drug that is in the same pharmacologic class or uses the same mechanism of action as the step therapy drug and was discontinued by the prescriber due to lack of efficacy, diminished effect, or an adverse event.

On granting a step therapy exception request, a carrier or PBM must authorize coverage for the prescription drug ordered by the prescriber for an insured or enrollee.

Procedures for Determinations by Private Review Agents

For a step therapy exception request or a prior authorization request for pharmaceutical services submitted electronically, a private review agent must make a determination in real time if (1) no additional information is needed to process the request and (2) the request meets the private review agent's criteria for approval. If a request is not approved in real time, the private review agent must make a determination within one business day after receiving all information necessary to make the determination.

Prohibition on Requiring Subsequent Prior Authorizations for Specified Prescriptions

A carrier or PBM may not require more than one prior authorization if two or more tablets of different dosage strengths of the same prescription drug are (1) prescribed at the same time as part of an insured's treatment plan and (2) manufactured by the same manufacturer. This prohibition does not apply if the prescription drug is an opioid that is not an opioid partial agonist.

Additional Provisions of the Bill

The bill may not be construed to (1) prevent a carrier or PBM from requiring an insured or enrollee to try an AB-rated generic equivalent or interchangeable biological product before providing coverage for the equivalent branded prescription drug; (2) prevent a health care provider from prescribing a prescription drug that is determined to be medically appropriate; or (3) require a carrier or PBM to provide coverage for a prescription drug that is not covered by a policy or contract of the carrier or PBM.

Current Law:

Step Therapy/Fail-first Protocols

"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 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.

Private Review Agents

A "private review agent" is a (1) nonhospital-affiliated person or entity performing utilization review that is either affiliated with, under contract with, or acting on behalf of a Maryland business entity or a third party that pays for, provides, or administers health care services to citizens of the State or (2) any person or entity performing utilization review for the purpose of making claims or payment decisions for health care services on behalf of the employer's or labor union's health insurance plan under an employee assistance program for employees other than the employees employed by the hospital or a business wholly owned by the hospital. A private review agent may not conduct utilization review in the State unless the Insurance Commissioner has granted the private review agent a certificate of registration.

Prior Authorizations for Prescription Drugs

Chapter 549 of 2019 established requirements for prior authorization for a prescription for a chronic condition and requires specified entities to (1) maintain a database of information relating to prior authorization requests filed electronically; (2) provide a specific explanation when denying a prior authorization; (3) honor certain prior authorizations for a specified time period and under specified circumstances; and (4) provide specified notice of a new prior authorization requirement for a prescription drug. If a carrier requires a prior authorization for a prescription drug, the prior authorization request must allow a health care provider to indicate whether a prescription drug is to be used to treat a chronic condition. If a health care provider indicates as such, a carrier may not request a reauthorization for a repeat prescription for one year or for the standard course of treatment for the chronic condition, whichever is less.

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 advises that the bill would undermine the use of step therapy protocols for certain drugs classes and could result in steep cost increases.

Additional Information

Prior Introductions: Similar legislation has not been introduced within the last three years; however, legislation with similar provisions has been proposed. See HB 1359 and SB 952 of 2020.

Designated Cross File: SB 515 (Senator Lam) - 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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