HB 1241

Department of Legislative Services

Maryland General Assembly
2016 Session

FISCAL AND POLICY NOTE
First Reader

House Bill 1241 (Delegates Kipke and Bromwell)
Health and Government Operations

Pharmacy Benefits Managers - Contracts With and Reimbursement of Pharmacists

This bill requires a pharmacy benefits manager (PBM) to (1) ensure that pricing information remains consistent with pricing changes and availability in the marketplace; (2) provide contracted pharmacies with a means to review pricing updates in a web-based or electronic format that is searchable; and (3) within three business days after a pricing information update, reimburse contracted pharmacies for drugs subject to maximum allowable cost (MAC) pricing based on the updated pricing information. A product on the list of drugs subject to MAC pricing must be eliminated from the list by the PBM within 24 hours after the PBM knew or should have known of a change in the pricing or availability of the product. The bill also alters requirements PBMs must meet prior to placing a drug on a MAC list and existing appeals procedures for contracting pharmacies to resolve issues regarding MAC pricing.

Fiscal Summary

State Effect: To the extent the bill restricts the number of generic drugs that may be placed on a MAC list, prescription drug expenditures for the State Employee and Retiree Health and Welfare Benefits Program (State Plan) increase by a significant amount beginning in FY 2017. Revenues are not affected.

Local Effect: None.

Small Business Effect: Meaningful for small business pharmacies that contract with PBMs.

Analysis

Bill Summary: The definition of "maximum allowable cost list" is altered to mean a list of drugs, medical products, and devices for which a MAC has been established by a PBM or a purchaser and on which reimbursement to a contracted pharmacy is based.

The bill specifies that each initial and renewal contract between a PBM and a contracted pharmacy must include the sources used to determine MAC pricing.

A PBM must maintain a procedure to eliminate products from the list of drugs subject to MAC pricing to remain consistent with pricing changes (as currently required) and availability in the marketplace.

Before placing a prescription drug on a MAC list, a PBM must ensure that the drug is listed as either "A" or "AB" (rather than "A" or "B") by the U.S. Food and Drug Administration (FDA) and that the drug is available for purchase by contracted pharmacies, including contracted retail pharmacies.

The process available to a contracted pharmacy to appeal, investigate, and resolve disputes regarding MAC pricing must include (1) a requirement that an appeal be filed by the contracted pharmacy no later than 21 days after the date of the initial adjudicated claim; (2) a requirement that, within 21 days after the date the appeal is filed, the PBM investigate and resolve the appeal and report to the contracted pharmacy on the PBM's determination; and (3) a requirement that the PBM provide the national drug code of a drug that is readily available for purchase and the name of the wholesale distributor from which the drug may be purchased by the contracted pharmacy at a price at or below the *MAC* determined by the PBM. If an appeal is upheld, a PBM must permit the appealing contracting pharmacy to reverse and rebill the claim – retroactive to the date the claim was originally adjudicated and have the correction be effective as to any subsequent similar claims.

Current Law: PBMs are businesses that administer and manage prescription drug benefit plans for purchasers. PBMs must register with the Maryland Insurance Administration prior to providing pharmacy benefits management services. The Insurance Commissioner is authorized to examine the affairs, transactions, accounts, and records of a registered PBM at the PBM's expense. PBMs are prohibited from shipping, mailing, or delivering prescription drugs or devices to a person in the State through a nonresident pharmacy unless the nonresident pharmacy holds a nonresident pharmacy permit from the State Board of Pharmacy.

Chapter 363 of 2014 requires a PBM to include the sources used to determine MAC pricing in each contract with a contracted pharmacy. A PBM must update pricing information at least every seven days and provide a means for contracted pharmacies to promptly review

pricing updates. A PBM must maintain a procedure to eliminate products from any MAC list. Before placing a prescription drug on a MAC list, a PBM must ensure that the drug meets specified criteria. Each contract between a PBM and a contracted pharmacy must include a process to appeal, investigate, and resolve disputes regarding MAC pricing.

A process to appeal, investigate, and resolve disputes regarding MAC pricing must reflect the following. An appeal must be (1) filed no later than 21 days after the date of the initial claim and (2) investigated and resolved within 21 days after the date the appeal is filed. A contracted pharmacy must be provided with a telephone number at which the pharmacy may speak to an individual responsible for processing appeals. A PBM must provide a reason for any appeal denial and the national drug code of any drug that may be purchased by the contracted pharmacy at a price at or below the benchmark price determined by the PBM. If an appeal is upheld, a PBM must make the change in the MAC no later than one business day after the date of determination on the appeal and permit the appealing contracting pharmacy to reverse and rebill the claim and any subsequent similar claims.

Background: "MAC" generally refers to a PBM-generated list of prescription drugs that includes the upper limit or maximum amount that a PBM will pay for generic drugs and brand-name drugs that have generic versions available (multisource brands). Each PBM establishes its own MAC list based on varying criteria, such as availability of the drug in the marketplace, whether the drug is obtainable from more than one manufacturer, how the product is rated by FDA in relation to the innovator drug, and price differences between the brand and generic products.

State Expenditures: FDA publishes a therapeutic equivalence rating for applicable multisource prescription drug categories in a publication known as the "Orange Book." Codes beginning with "A" signify the product is deemed therapeutically equivalent to the reference product for the category. The "AB" code means a drug meets necessary bioequivalence requirements. Codes beginning with "B" indicate bioequivalence has not been confirmed.

The Department of Budget and Management (DBM) advises that, by requiring that a prescription drug be listed as "A" or "AB" (rather than "A" or "B") before being placed on a MAC list, the bill limits the number of generic drugs that can be included on MAC lists. DBM notes that MAC lists save the State Plan money by ensuring fair reimbursement for generic drugs. To the extent certain generics can no longer be placed on a MAC list, State Plan expenditures increase significantly beginning in fiscal 2017; according to DBM, by as much as 2% of drug costs overall or an estimated $9.9 million annually.

Additional Information

Prior Introductions: None.

Cross File: None.

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

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