SB 825

Department of Legislative Services

Maryland General Assembly
2014 Session

FISCAL AND POLICY NOTE

Senate Bill 825 (Senator Pugh)
Finance

Pharmacy Benefits Managers - Specialty Drugs

This bill requires a pharmacy benefits manager (PBM) to designate on its formulary which prescription drugs are a "Tier I specialty drug" or "Tier II specialty drug." A PBM must allow any pharmacy to dispense a Tier I specialty drug if the pharmacy holds a pharmacy permit in the State and is authorized by a wholesale distributor to purchase the Tier I specialty drug. A PBM must allow any licensed pharmacist or any pharmacy that holds a Maryland pharmacy permit to dispense a prescription for a Tier II specialty drug if the pharmacist or pharmacy (1) holds a contract with the PBM; (2) has the Tier II specialty drug in inventory or has ready access to the drug; and (3) is capable of complying with any special handling/administration, unique inventory management, high level of patient monitoring, or more intense patient support requirements.

Fiscal Summary

State Effect: Special fund expenditures for the Maryland Insurance Administration (MIA) increase by $51,700 in FY 2015 to hire one full-time analyst to handle the filing of formularies, disputes regarding designation of specialty drugs, and any related appeals. Prescription drug expenditures for the State Employee and Retiree Health and Welfare Benefits Program (the State plan) increase beginning in FY 2015. The exact amount of such increase cannot be reliably estimated at this time. Any additional workload on the State Board of Pharmacy and the University of Maryland School of Pharmacy can be handled with existing budgeted resources. Future years reflect annualization and inflation. Revenues are not affected.

(in dollars)	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019
Revenues	$0	$0	$0	$0	$0
SF Expenditure	51,700	65,000	68,100	71,300	74,700
GF/SF/FF Exp.	-	-	-	-	-
Net Effect	(-)	(-)	(-)	(-)	(-)

Note:() = decrease; GF = general funds; FF = federal funds; SF = special funds; - = indeterminate effect

Local Effect: Prescription drug expenditures for local governments may increase.

Small Business Effect: Potential meaningful. Prescription drug expenditures for small businesses may increase.

Analysis

Bill Summary: "Tier I specialty drug" means a prescription drug that (1) is not routinely dispensed at a majority of retail pharmacies due to physical or administrative requirements; (2) includes nonoral chemotherapy drugs, nonoral radiation drugs, intravenous therapy drugs, or other drugs that require physical facilities for preparation; (3) is used to treat complex, chronic, or rare medical conditions; (4) requires special handling or storage or has distribution or inventory limitations; (5) has a complex dosing regimen or requires specialized administration; (6) is considered by the U.S. Food and Drug Administration (FDA) to have restricted distribution; (7) requires complex and extended patient education or counseling, intensive monitoring, or clinical oversight; and (8) has significant side effects or a significant risk profile.

"Tier II specialty drug" means a prescription drug that requires (1) special handling; (2) special administration; (3) unique inventory management; (4) a high level of patient monitoring; or (5) more intense patient support than conventional therapies.

A PBM may not require a Tier I or Tier II specialty drug to be dispensed by mail order. A PBM may not impose any cost sharing or other condition on a beneficiary for a Tier I or Tier II specialty drug obtained from a noncommunity pharmacy that is not imposed for such drugs from a community pharmacy if the benefits are provided under the same program, policy, or contract. A PBM may not impose a copayment or coinsurance requirement that exceeds $150 for up to a 30-day supply of a covered Tier I or Tier II specialty drug. The bill requires a PBM to allow certain pharmacies and pharmacists to dispense Tier I and Tier II specialty drugs. A PBM must reimburse a retail pharmacy for a Tier I or Tier II specialty drug at the current preferred brand tier reimbursement rate specified in the contract between the PBM and the retail pharmacy.

A PBM must designate on its formulary the prescription drugs that are Tier I specialty drugs as well as those that are Tier II specialty drugs. A PBM must then submit a list of the prescription drugs the PBM has designated as Tier I specialty drugs to the Insurance Commissioner and update the list every 90 days. If a pharmacist or pharmacy disputes the designation of a Tier I or Tier II specialty drug, the pharmacist or pharmacy may request a determination from the Insurance Commissioner. On request, MIA, in consultation with the State Board of Pharmacy and the University of Maryland School of

Pharmacy, must make a determination as to whether the prescription drug is a Tier I or Tier II specialty drug within 30 days. A PBM must change the designation of a Tier I or Tier II specialty drug in accordance with the determination of the Insurance Commissioner.

Current Law: PBMs are businesses that administer and manage prescription drug benefit plans for purchasers. PBMs must register with MIA 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.

Section 15-805 of the Insurance Article prohibits a health insurance policy or contract from imposing a copayment, deductible, or other condition on an insured or certificate holder that uses the services of a community pharmacy that is not imposed when the insured or certificate holder uses the services of a mail order pharmacy, if the benefits are provided under the same program, policy, or contract. Under § 15-806 of the Insurance Article, a nonprofit health service plan that provides pharmaceutical services must allow a subscriber, member, or beneficiary to fill prescriptions at the pharmacy of the subscriber's, member's, or beneficiary's choice.

Background: Most prescription drug coverage includes a three-tiered copayment arrangement under which enrollees pay a specific dollar amount for each prescription in a given tier of drugs (*i.e.*, generic, preferred brand name, and nonpreferred brand name). Recently, some insurance companies have begun offering drug plans with coinsurance under which a member pays a percentage of the drug cost rather than a fixed-dollar copayment. Other carriers have implemented a "fourth tier" for specialty drugs, which generally includes prescription medicines used to treat complex, chronic conditions.

In 2013, Delaware enacted legislation that limits coinsurance or copayment amounts for specialty tier drugs to $150 per month for up to a 30-day supply of any single specialty tier drug. Patients may also request an exception to obtain a specialty drug that would not otherwise be available on a health plan formulary.

In its 2013 *Drug Trend Report*, Express Scripts (one of the largest PBMs) notes that less than 1% of prescriptions filled in 2012 were for specialty medications, yet specialty drugs accounted for 25% of total prescription drug expenditures. While utilization of the top 10 commercial specialty therapy classes *declined* marginally (0.4%), total costs for specialty drugs increased by 18.4%, largely driven by the availability of newer, more expensive therapies. By 2019 or 2020, specialty drugs are expected to represent 50% of overall drug spending. The top three therapy classes (inflammatory conditions, multiple sclerosis, and cancer) are expected to account for more than 50% of that overall spending. The report further notes that at least 60% of the new drugs expected to gain approval from the FDA in 2013 alone will be specialty drugs.

State Expenditures: Special fund expenditures for MIA increase by $51,693 in fiscal 2015, which reflects the bill's October 1, 2014 effective date. This estimate reflects the cost of hiring one full-time analyst to handle the quarterly filing of PBM specialty drug formularies and storage of such information, disputes regarding designation of specialty drugs on the formularies, and any related appeals. It includes a salary, fringe benefits, one-time start-up costs, and ongoing operating expenses.

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Salary and Fringe Benefits	$46,888
One-time Start-up Expenses	4,370
Ongoing Operating Expenses	435
Total FY 2015 State Expenditures	**$51,693**

Future year expenditures reflect a full salary with annual increases and employee turnover as well as annual increases in ongoing operating expenses.

State plan expenditures for prescription drug coverage increase by an unknown amount beginning in fiscal 2015. The Department of Budget and Management (DBM) advises that this increase is attributable to the bill's provision authorizing patients to fill a Tier I specialty drug prescription at any pharmacy licensed in the State that either stocks the medication or can easily obtain it. DBM notes that, while the State plan does not limit the filling of specialty medications to mail-order pharmacies, it does restrict prescription services to pharmacies within the contracted PBM's network. As the bill prohibits such a requirement, State plan expenditures increase. The exact amount of any increase cannot be reliably estimated at this time.

Additional Comments: SB 874/HB 761 of 2014, among other things, prohibit a PBM from imposing a copayment or coinsurance requirement that exceeds $150 for up to a 30-day supply of certain covered specialty drugs.

Additional Information

Prior Introductions: None.

Cross File: HB 875 (Delegate Kipke, *et al.*) - Health and Government Operations.

Information Source(s): Express Scripts 2013 *Drug Trend Report*, Maryland Insurance Administration, Department of Budget and Management, University System of Maryland, Department of Legislative Services

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