Department of Legislative Services

Maryland General Assembly
2015 Session

FISCAL AND POLICY NOTE
Revised

Senate Bill 606 (Senator Pugh, *et al.*)
Finance Health and Government Operations

Health Insurance - Abuse-Deterrent Opioid Analgesic Drug Products - Coverage

This bill requires insurers, nonprofit health service plans, and health maintenance organizations (collectively known as carriers) that provide prescription drug coverage (including coverage provided through a pharmacy benefits manager) to provide coverage for specified "abuse-deterrent opioid analgesic drug products."

The bill takes effect January 1, 2016, 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: State Employee and Retiree Health and Welfare Benefits Program (State plan) expenditures increase by a minimal amount beginning in FY 2016 due to decreased enrollee cost sharing for certain prescription drugs. Minimal special fund revenue increase for the Maryland Insurance Administration (MIA) from the $125 rate and form filing fee in FY 2016. Review of filings can be handled with existing budgeted MIA resources.

Local Effect: Expenditures may increase by a minimal amount for some local governments due to decreased enrollee cost sharing for certain prescription drugs.

Small Business Effect: None. The bill does not apply to the small group market.

Analysis

Bill Summary: "Abuse-deterrent opioid analgesic drug product" means a brand name or generic opioid analgesic drug product approved by the U.S. Food and Drug Administration (FDA) with abuse-deterrent labeling that indicates the drug product is expected to result in

a meaningful reduction in abuse. "Opioid analgesic drug product" means a drug product that contains an opioid agonist and is indicated by FDA for the treatment of pain, regardless of whether the drug product is in immediate or extended release form or contains other drug substances.

Coverage must be provided for (1) at least two brand-name abuse-deterrent opioid analgesic drug products, each containing different analgesic ingredients and (2) if available, at least two generic abuse-deterrent opioid analgesic drug products, each containing different analgesic ingredients. Each brand-name or generic drug product must be on the lowest cost tier for brand-name or generic prescription drugs on the carrier's drug formulary, respectively.

Carriers are prohibited from requiring an insured or enrollee to first use an opioid analgesic drug product without abuse-deterrent labeling before providing coverage for an abuse-deterrent opioid analgesic drug product covered on the entity's prescription drug formulary.

Carriers may undertake utilization review, including preauthorization, for abuse-deterrent opioid analgesic drug products covered by the carrier, if the same requirements are applied to nonabuse-deterrent opioid analgesic drug products covered by the carrier in the same formulary tier as the abuse-deterrent opioid analgesic product.

Current Law: Statute includes 45 mandated health insurance benefits that certain carriers must provide to their enrollees.

Background: Prescription opioid analgesics are an important component of modern pain management. However, abuse and misuse of these products have created a serious and growing public health problem. According to FDA, one potentially important step toward creating safer opioid analgesics has been the development of opioids that are formulated to deter abuse. Abuse-deterrent formulations may include physical/chemical barriers, agonist/antagonist combinations, altered deliver systems, or prodrugs (those that lack opioid activity until transformed in the gastrointestinal tract).

FDA issued draft guidance to assist pharmaceutical manufacturers in creating abuse-deterrent opioid formulations; final guidance is expected by June 2015. To date, only four prescription drugs have been approved by FDA as abuse-deterrent opioids: Embeda (morphine sulfate/naltrexone HCl), Hysingla (hydrocodone), a new formulation of OxyContin (oxycodone), and Targiniq ER (oxycodone/naloxone).

Several states are considering legislation mandating health insurance coverage of abuse-deterrent opioid analgesic drug products, including Connecticut, Florida, Illinois, Kansas, and Virginia.

State Expenditures: State plan expenditures increase by a minimal amount in fiscal 2016.

According to the Department of Budget and Management (DBM), all four of the prescription drugs currently approved by FDA as abuse-deterrent opioids are currently covered on the State plan's prescription drug formulary. OxyContin is a preferred brand-name drug with a copayment of $25 for a 45-day supply/$50 for a 90-day supply, while the remaining drugs are nonpreferred brand-name drugs subject to a copayment of $40/$80, respectively. Under the bill, for each prescription other than OxyContin, the State plan is required to charge the lower preferred brand-name copayment, at an increased State plan cost of $15 to $30 per prescription. DBM indicates that fewer than 25 prescriptions for such drugs have been filled in the past year. Therefore, any additional cost to the State plan is anticipated to be minimal.

In future years, to the extent that the number of abuse-deterrent opioids prescribed to State plan enrollees increases (which is likely as the number of prescription drugs approved by FDA as abuse-deterrent opioids increases), State plan expenditures also increase.

Local Expenditures: Local government expenditures (for those that purchase fully insured plans from an insurance company) may increase by a minimal amount for some local governments beginning in fiscal 2016 due to increased prescription drug costs to the extent copayments are limited under the bill.

Additional Comments: The federal Employee Retirement Income Security Act preempts states' ability to require private employers to offer insurance coverage and exempts the coverage offered by self-insured entities from state insurance regulation. Thus, insured health benefit plans (those purchased directly from a carrier) are subject to Maryland's mandated benefits law, while other (self-insured) employment-based plans are not. According to MIA, of the total number of covered lives enrolled in commercial health insurance in the State in 2013, only 37.1% were in plans subject to State regulation, while 62.9% were in plans not subject to such regulation.

Additional Information

Prior Introductions: None.

Cross File: HB 887 (Delegate K. Young, *et al.*) - Health and Government Operations.

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

Fiscal Note History: First Reader - March 2, 2015
md/ljm Revised - Senate Third Reader/Updated Information - March 31, 2015

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