HB 546

Department of Legislative Services

Maryland General Assembly
2019 Session

FISCAL AND POLICY NOTE
First Reader

House Bill 546 (Delegate Kipke, *et al.*)
Health and Government Operations

Health Insurance - Access to and Coverage of Specialty Drugs - Definition

This bill specifies that the current definition of "specialty drug" applies only to current limits on copayments and coinsurance requirements for such drugs and specified coverage determination decisions. The bill establishes a new definition of "specialty drug" for purposes of a carrier requiring a specialty drug to be obtained through a specified designated pharmacy and coverage of a specialty drug through a managed care system. **The bill takes effect January 1, 2020, 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: Special fund revenues increase minimally for the Maryland Insurance Administration (MIA) from the $125 rate and form filing fee in FY 2020 only. MIA review of additional filings may necessitate contractual support in FY 2020 only. No effect of the State Employee and Retiree Health and Welfare Benefits Program.

Local Effect: Local government finances and operations are not materially affected.

Small Business Effect: Meaningful.

Analysis

Bill Summary/Current Law: A new definition of "specialty drug" is established to mean a prescription drug that (1) is designated as a limited distribution drug by the U.S. Food and Drug Administration; (2) is not available in an oral or self-administered formulation; or (3) requires special handling above and beyond refrigeration or patient counseling. Nothing in the Insurance Article (or regulations adopted under the article) precludes a

carrier from requiring a covered "specialty drug" (new definition) to be obtained through a designated pharmacy or other authorized source or a pharmacy participating in the carrier's network, if the pharmacy meets certain performance standards and accepts the carrier's network reimbursement. A carrier is also permitted to provide coverage for "specialty drugs" (new definition) through a managed care system.

Further, as under current law, a pharmacy registered under § 340B of the federal Public Health Services Act may apply to an entity to be a designated specialty pharmacy for the purpose of enabling the pharmacy's patients with HIV, AIDS, or hepatitis C to receive a specified copayment or coinsurance maximum if the pharmacy is owned by a federally qualified health center that provides integrated and coordinated medical and pharmaceutical services to HIV positive, AIDS, and hepatitis C patients and the prescription drugs are covered "specialty drugs" (new definition) for the treatment of HIV, AIDS, or hepatitis C.

The current law definitions of "specialty drug" and associated terms are recodified in a new section. Under the existing definition, "specialty drug" means a prescription drug that (1) is prescribed for an individual with a complex or chronic medical condition or a rare medical condition; (2) costs $600 or more for up to a 30-day supply; (3) is not typically stocked at retail pharmacies; and (4) requires a difficult or unusual process of delivery to the patient in the preparation, handling, storage, inventory, or distribution of the drug or requires enhanced patient education, management, or support, beyond that required for traditional dispensing before or after administration of the drug.

"Complex or chronic medical condition" means a physical, behavioral, or developmental condition that may have no known cure, is progressive, or can be debilitating or fatal if left untreated or undertreated, such as multiple sclerosis, hepatitis C, and rheumatoid arthritis. "Rare medical condition" means a disease or condition that affects fewer than 200,000 individuals in the United States or approximately 1 in 1,500 individuals worldwide, such as cystic fibrosis, hemophilia, and multiple myeloma.

Under the bill, the current law definition applies only with respect to the prohibition against a carrier imposing a copayment or coinsurance requirement on a covered "specialty drug" (existing definition) that exceeds $150 for up to a 30-day supply. This limit must be increased annually to reflect medical care inflation.

Current law regarding a determination by a carrier that a prescription drug is not a specialty drug (existing definition) being a coverage decision for purposes of an appeal is also recodified. If a carrier determines that a prescription drug is not a specialty drug on the basis that it is not prescribed for an individual with a complex or chronic medical condition or a rare medical condition, the Insurance Commissioner may seek advice from an independent review organization or medical expert at the expense of the carrier.

Small Business Effect: Small business pharmacies may provide specialty drugs under the bill.

Additional Comments: Related legislation has been previously introduced to broaden or modify the types of pharmacies that can be used to obtain specialty drugs. House Bill 1117 of 2017 received a hearing from the House Health and Government Operations Committee but was withdrawn. Senate Bill 1018 of 2016 received a hearing in the Senate Finance Committee, but no further action was taken. Its cross file, House Bill 1383, received a hearing in the House Health and Government Operations Committee but was withdrawn.

Additional Information

Prior Introductions: HB 1183 and SB 1076 of 2018 were withdrawn.

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 - March 6, 2019
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