This bill prohibits an insurer, nonprofit health service plan, and health maintenance organization (collectively known as carriers) from imposing a copayment or coinsurance requirement on a covered “specialty drug” that exceeds $150 for up to a 30-day supply. This limit must be increased annually to reflect medical care inflation. A carrier may provide coverage for specialty drugs through a managed care system. The bill also specifies that nothing in the Insurance Article (or regulations adopted under the Article) precludes a carrier from requiring a covered specialty drug 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.

The bill applies to all policies, contracts, and health benefit plans issued, delivered, or renewed in the State on or after January 1, 2016.

Fiscal Summary

State Effect: Potential minimal special fund revenue increase for the Maryland Insurance Administration (MIA) from the $125 rate and form filing fee in FY 2016. Review of any potential filings can be handled by existing MIA personnel. No effect on the State Employee and Retiree Health and Welfare Benefits Program (State plan).

Local Effect: The bill is not expected to significantly affect local government operations or finances; any impact depends on current cost sharing for specialty drugs.

Small Business Effect: Potential minimal.
Analysis

Bill Summary: “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.

“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 those required for traditional dispensing, before or after administration of the drug.

A determination by a carrier that a prescription drug is not a specialty drug is considered a coverage decision for purposes of an appeal. 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.

A pharmacy registered under § 340B of the federal Public Health Services Act (a 340B pharmacy) may apply to a carrier to be a designated pharmacy for the purpose of enabling the pharmacy’s patients with HIV, AIDS, or hepatitis C to receive the copayment and coinsurance maximum provided under the bill. A 340B pharmacy may apply if (1) the pharmacy is owned by a federally qualified health center; (2) the pharmacy provides certain services to HIV+, AIDS, and hepatitis C patients; and (3) the prescription drugs are covered specialty drugs for the treatment of such diseases.

Current Law: 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 pharmacy benefits managers) 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 U.S. Food and Drug Administration in 2013 alone will be specialty drugs.

CareFirst BlueCross BlueShield observed increased medication adherence in its patient population when medication was ordered through its specialty pharmacy network. Increased adherence rates may result in savings through reduced hospitalizations and emergency department utilization.

**Additional Comments:** SB 825/HB 875 of 2014, among other things, prohibit a pharmacy benefits manager 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:** SB 874 (Senator Klausmeier) - Finance.