

Maryland Prescription Drug Affordability Board: Generics Report

Prescription Drug Affordability Stakeholder Council
Member Orientation

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MARYLAND
Prescription Drug Affordability Board

Generics Report

Generics Report (Ch. 425 of the Acts of 2020, sect. 5)- conduct a one-time study of the operation of the generic drug market in the United States that includes a review of physician-administered drugs and considers:

- (i) the prices of generic drugs on a year-over-year basis;
- (ii) the degree to which generic drug prices affect yearly insurance premium changes;
- (iii) annual changes in insurance cost-sharing for generic drugs;
- (iv) the potential for and history of drug shortages;
- (v) the degree to which generic drug prices affect yearly State Medicaid spending; and
- (vi) any other relevant study questions; and (2) report its findings to the General Assembly, in accordance with § 2-1246 of the State Government Article



Generics Report- General Findings

1. Overview of Generic Drugs
 1. Definitions
 2. History
2. Role and Impact of Generics
 1. Utilization
 2. Trends
 3. Impact/Savings
3. Issues in the Generics Market



Overview- What is a Generic Drug?

Generic Drugs- Drugs approved by an abbreviated new drug application (ANDA) created to be the same as an already marketed brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use.

Authorized Generic- an approved brand name drug that is marketed without the brand name on its label. Other than the fact that it does not have the brand name on its label, it is the exact same drug product as the branded product. The manufacturer may choose to sell an authorized generic at a lower cost than the brand name drug



History

- Generic Drug approval process created by Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act)
 - Prior to 1984, generic drugs went through the full approval process
 - Less than 20% of prescriptions were generics
- Created the social contract that we have today:
 - The government grants a monopoly through exclusivities for name brand drugs for manufacturers to recoup the investment and reward risk and innovation
 - After that exclusivity ends, generics come to the market and dramatically reduce the cost
- FDA has approved 16,000 ANDAs since 1984



Generics: Role and Impacts

Utilization:

- Nationally, about 90% of prescriptions filled are for generic drugs
- Generic drugs make up less than 20% of total spending on prescription drugs

Savings:

- Nationally account for \$338 billion in US health systems savings in 2020
 - \$53.8 billion in Medicaid savings
- Maryland: \$5.6 billion in savings in 2020



Generics Report: Findings

- The prices of generic drugs on a year–over–year basis
 - Generics are a general driver of price deflation
 - Volume of generics continues to increase, while percentage of spending continues to decrease
- The degree to which generic drug prices affect yearly insurance premium changes;
 - Generics make up 3% of total health care spending, and likely have deflationary impact



Generics Report: Findings

- Annual changes in insurance cost-sharing for generic drugs;
 - Copay Steady vs Name Brand:
 - Generic Copays: 2018: \$6.06, 2019: \$5.63, 2020: \$6.97, 2021: \$6.61
 - Name Brand Copays: 2018: \$40.30; 2019: \$40.65, 2020: \$56.32, 2021: \$55.82
- The degree to which generic drug prices affect yearly State Medicaid spending;
 - Total Medicaid Savings: 2017: 2018: \$46.8, 2019: \$48.5, 2020: \$53.8 billion



Issues in the Generic Market

- Price Increases
 - While there is general deflationary pressure from new generics coming to market, there are frequently price increases in generics that are already on the market
 - Some potentially large price hikes
- Many drugs do not have adequate competition
 - Prices can be so low as to not attract adequate competition
 - Can sometimes result in single manufacturers and natural monopolies
- Shortages
 - Competition can drive prices so low, that the generics supply chain can become fragile; minor supply chain issues can cause major shortages
- Concerns about Quality

