

Study of the Operation of the Generics Drug Market

Maryland Prescription Drug Affordability Board

June 1, 2022



MARYLAND
Prescription Drug Affordability Board

Van T. Mitchell
Board Chair

Gerard Anderson, Ph.D.
Board Member

Eberechukwu Onukwugha, MS, Ph.D.
Board Member



MARYLAND
Prescription Drug Affordability Board

Renee Bovellet, M.D.
Board Member

Joseph Levy, Ph.D.
Board Member

Van T. Mitchell
Board Chair

For further information concerning this document, please contact:

Andrew York, Pharm.D., J.D.

Executive Director

16900 Science Drive, Suite 112-114

Bowie, MD 20715

410.804.0251

Andrew.York@maryland.gov

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The Prescription Drug Affordability Board's website address:

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Executive Summary

Introduction

In 2019, the Maryland General Assembly created the Maryland Prescription Drug Affordability Board (the Board) and directed the Board to conduct a one-time study of the operation of the generic drug market. This study includes a review of physician-administered drugs and:

- (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.

2019 Maryland Laws Ch. 692, § 5 (uncodified) (H.B. 768), amended by 2020 Maryland Laws Ch. 425. In this document, the Board reports its findings about the generics market—nationwide and in Maryland—and its recommendations for policies that support a robust and dynamic generic drug market.

Overview

Generic prescription drugs provide a less costly alternative to their brand-name counterparts by fostering price competition between generic and brand-name manufacturers. Since Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984¹ (also known as the Hatch-Waxman Act), and created a streamlined process for bringing generic drugs to market, the U.S. Food and Drug Administration (FDA) has approved over 16,000 generic drug applications. Generic drug utilization remains high. In 2019, generic drugs represented 90% of the drugs dispensed in the United States, but less than 20% of overall prescription drug spending.² Because generic drugs are typically less expensive than brand-name drugs, the American public

¹ [Drug Price Competition and Patent Term Restoration Act of 1984 \(Hatch-Waxman Act\), Pub. L. No. 98-417, 98 Stat. 1585 \(1984\).](#)

² [Association for Accessible Medicines \(AAM\) 2021 U.S. Generic and Biosimilar Medicines Savings Report. October 2021. Link Verified: June 1, 2022.](#)

spent \$338 billion dollars less on generic drugs in 2020 than it would have spent on equivalent brand-name drugs.³ This represents an estimated reduction in 2020 drug costs of \$5.6 billion for Maryland residents.⁴ Absent robust competition within the generics market, some generic drugs command high prices and others have experienced significant price increases. The Board is charged with identifying affordability challenges associated with high-cost generic drugs that undergo dramatic price increases.⁵

Key Findings

- 1. With Some Exceptions, Generic Drug Prices are Stable on a Year–Over–Year Basis**
 - 1.1. Aggregate generic prices are generally stable or decreasing
 - 1.2. Outlier drugs reflect price increases
- 2. Generic Drug Prices Have Minimal Impact on Insurance Premiums**
 - 2.1. Maryland health insurer data suggests that generic drugs may have lowered annual insurance premiums, especially when new generics come to market and compete with higher-cost, brand-name drugs.
 - 2.2. Generic drugs represent only 4% of overall health care spending. As a result, changes in generic costs are not likely to significantly impact insurance premiums.
 - 2.3. However, the prices of specific generic drugs can impact specific individuals when they are high-priced or have rapid price increases.
- 3. Cost–Sharing for Generic Drugs is Stable**
 - 3.1. Annual changes in insurance cost-sharing for generic drugs has remained stable at the national level.
 - 3.2. The current national average copay for generic drugs is estimated to be \$6.61 (compared to an average out-of-pocket (OOP) cost for brand-name drugs of \$55.82).⁶
- 4. Drug Shortages are an Important Challenge for Maryland Patients and Providers that Requires Further Study**

³ [AAM 2021 U.S. Generic and Biosimilar Medicines Savings Report. October 2021. Link Verified: June 1, 2022.](#)

⁴ [AAM 2021 U.S. Generic and Biosimilar Medicines Savings Report. October 2021. Link Verified: June 1, 2022.](#)

⁵ One of the Board legislative metrics for identifying drugs that may cause affordability issues is for generic drugs with a wholesale acquisition cost (WAC) of more than \$100 per 30-day supply *and* increase by 200% or more in an immediately preceding 12-month period.

⁶ [AAM 2021 U.S. Generic and Biosimilar Medicines Savings Report. October 2021. Link Verified: June 1, 2022.](#)

- 4.1. Shortages for essential generic drugs, especially physician-administered drugs, continue to be major issues for health systems.
- 4.2. Shortages often occur because manufacturers choose not to produce drugs with low profitability and because the supply chain for these drugs can be extremely fragile.
- 4.3. This feature represents a small proportion of the generics supply chain but creates major challenges for specific patients and providers.
- 4.4. Many of the raw ingredients are manufactured in China and India.
5. **The Effect of Generic Drugs on State Medicaid Spending is Unquantifiable Based on Available Data**
 - 5.1. Rebates to Medicaid through the Medicaid Drug Rebate Program make it difficult to attribute the actual price reductions from generics to the Medicaid program.
 - 5.2. This is because brand-name drugs are required to provide Medicaid-specific rebates that can make them less expensive than their generic alternatives.
 - 5.3. This typically occurs when the branded drug has rapidly increased in price.

Ongoing Issues in the Generics Market

1. **Dramatic Price Increases for Specific Products** – While the generics market represents a competitive market overall, certain generic drugs have experienced large price hikes; these are typically drugs with a small market.
2. **Insufficient Market Competition for Some Products, Including Price Fixing for Some Products** – Some prescription drugs have only one or two suppliers. The Department of Justice has found that some generic manufacturers are working together to fix prices for certain generic drugs.
3. **Supply Chain** – The raw materials used to manufacture generic drugs are commonly made in China and India, and shortages can occur if their supply is disrupted.
4. **Quality and Safety of the Generic Drug Supply Chain** – FDA-approved generic drugs are found to be safe and equally effective as their brand-name alternatives. There have been some recent concerns about specific drugs.
5. **Barriers to Generics Market Entry** – There are many cases of generics not entering the market as quickly as they should. Brand-name drugs often engage in “evergreening” tactics to extend their patents and FDA-granted exclusivities beyond the intended timeframe.
6. **Generic Drugs are Not Favored on Formularies** – There may be an increasing trend of generics receiving less-favorable placement on formularies than

brand-name drugs. Pharmacy benefit managers (PBMs) can earn higher rebates on branded rather than generic drugs; this may be a source of increased cost for the health care system.

Recommendations

1. The Board, with its Maryland state partners, should evaluate policies to identify and address affordability challenges for generic drugs with high prices or high price increases.
2. The Board, with its Maryland state partners, should explore opportunities to collect data to better understand and address the issues outlined in this report.
3. The Board, with its Maryland state partners, should evaluate waste-free formularies as a policy to promote savings through generic drugs.
4. The Board, with its Maryland state partners, should explore policies to address drug shortages in Maryland.
5. The Board, with its Maryland state partners, should explore partnerships and policies to support a safe and robust supply chain for generic drugs in Maryland.

1. Introduction

In 2019, the Maryland General Assembly created the Maryland Prescription Drug Affordability Board (the Board) and directed the Board to conduct a one-time study of the operation of the generic drug market. The study includes a review of physician-administered drugs and:

- (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.

In this document, the Board reports its findings about the generics market—nationwide and in Maryland—and its recommendations for policies that support a robust and dynamic generic drug market.

2. Background: Generic Drug Definitions and History

2.1. What are Generic Drugs?

A generic drug is a medication created to have the same chemical compound as an already-marketed, brand-name drug and is the same in terms of dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use.⁷

Through patent and market exclusivities, brand-name drugs enjoy government-granted monopolies that allow the brand-name manufacturers to set prices, enabling the companies to earn returns on their investments and incentivize future innovation. Once those patents and market exclusivities expire, generic drugs may enter the market to compete with the brand-name drugs. Once multiple generics are available on the market, generic prices are generally substantially lower.

⁷ [FDA. Generic Drugs: Questions & Answers. January 2021. Link Verified: June 1, 2022.](#)

2.2. Definitions Related to Generic Drugs

The term “generic drugs” refers to drugs that are approved under the Abbreviated New Drug Application (ANDA) approval pathway⁸ as opposed to the New Drug Application (NDA) pathway⁹ for brand-name drugs. This process is available for small-molecule drugs, but not the more complex biological drugs (biologics), as described below.

Generic drug applications are termed "abbreviated" because they are generally not required to include preclinical and clinical data to establish safety and effectiveness. Instead, generic applicants must demonstrate bioequivalence to (i.e., that they perform the same as) the brand-name drug. Because the preclinical and clinical trials are some of the most expensive components of bringing a drug to market, this abbreviated pathway allows manufacturers to bring generic versions of the drugs to market more quickly and at a lower cost. Since a generic drug is substitutable with brand-name and other generic drugs, robust competition incentivizes manufacturers to produce and sell the drug at the lowest possible price—that is, at an amount that approaches the marginal cost of production.

“Multiple source”, or “multi-source”, drugs refer to drugs that have two or more manufacturers producing one or more therapeutically equivalent generic drugs. Many databases, as well as research and reports based on those databases, use this term. In this report, the terms multi-source drugs and generic drugs will be used synonymously.

An “authorized generic” is an approved, brand-name drug that is marketed without the brand name on its label. Although it does not have the brand name on its label, an authorized generic is the same drug product as the branded entity, produced by the same manufacturer.¹⁰ The manufacturer does not give up their market exclusivities through this process. Authorized generics are marketed under the brand-name company’s NDA. They can be marketed by the brand-name drug company or another company with the brand company’s permission. Authorized generics allow brand-name manufacturers to sell their drugs at lower costs than the brand-name drug, which may be locked in at a higher list price due to contracting and coverage pressures.

⁸ [FDA. Abbreviated New Drug Application \(ANDA\). January 2022. Link Verified: June 1, 2022.](#)

⁹ [FDA. New Drug Application \(NDA\). January 2022. Link Verified: June 1, 2022.](#)

¹⁰ [FDA List of Authorized Generic Drugs. March 2022. Link Verified: June 1, 2022.](#)

The 505(b)(2) New Drug Application pathway¹¹ (often known as a “hybrid application”) is a streamlined NDA process for new branded drugs that uses existing data from studies conducted by or for entities other than the applicants. For example, follow-on insulins—Basaglar in 2015 (insulin glargine, Lilly) and Admelog in 2017 (insulin lispro, Sanofi)—were approved through this pathway. Although they are not generics, drugs approved under the 505(b)(2) pathway can create market competition and can decrease prices for competing molecules, similar to the biosimilar market.¹²

Finally, “biosimilars” refer to biological products that are approved through the abbreviated 351(k) pathway,¹³ rather than the standard 351(a) Biologics License Application (BLA) pathway for the approval of biologic products.¹⁴ Biologics approved through a standalone BLA are called reference products. All biosimilars are deemed to be highly similar to, and have no clinically meaningful differences in safety, purity, and potency (safety and effectiveness) from, an existing FDA-approved reference product. However, not all biosimilars can be used interchangeably with the reference biologic. Instead, only a subset of biosimilars is approved as interchangeable products, allowing for the substitution and interchangeability that makes the generics market highly competitive.¹⁵

2.3. History of Generic Drugs

Prior to 1984, both brand-name and generic drugs were approved under the same FDA approval pathway, which required the same investment in pre-clinical and clinical data. If a version of a drug was already in the market, it may not have been profitable for other manufacturers to bring a generic drug to market because market competition would drive the price down and the manufacturer would be unable to recuperate its initial investment.

¹¹ [FDA. Abbreviated Approval Pathways for Drug Product: 505\(b\)\(2\) or ANDA?. September 2019. Link Verified: June 1, 2022.](#)

¹² [Levy J., Chowdhury Z., and Socal M. Changes Associated With the Entry of a Biosimilar in the Insulin Glargine Market. JAMA Intern Med. 2021;181\(10\):1405-1407.](#)

¹³ [FDA. Biosimilar Development, Review, and Approval. October 2017. Link Verified: June 1, 2022.](#)

¹⁴ [FDA. Biologics License Applications \(BLA\) Process \(CBER\). January 2021. Link Verified: June 1, 2022.](#)

¹⁵ The topic of biosimilars is not directly addressed in this report but will be addressed in-depth in future reports. Some states do not permit the interchangeability of biosimilars.

As a result, many brand-name drugs were able to command monopoly prices. Prior to 1984, only 20% of dispensed drugs were generics.¹⁶

By establishing an abbreviated pathway for generic drugs, the Drug Price Competition and Patent Term Restoration Act of 1984 (also known as the Hatch-Waxman Act) effectively created a societal contract within the prescription drug market. The Act provides an approval pathway and government-granted monopoly, through patents and market exclusivities, for a brand-name drug; this allows the manufacturer to recuperate its investment and earn a profit for a certain time period. Such profits incentivize continued innovation. After these market exclusivities expire, generic drugs can come to market more quickly and at lower costs under the abbreviated pathway. Savings in time and approval costs allow the generics manufacturers to charge lower prices for the generic drugs, thereby driving prices down towards the marginal cost of production.

The cost of bringing a new brand-name drug to market ranges from \$300 million to over \$3 billion,¹⁷ compared to an estimated cost of between \$1 million and \$5 million to bring a generic drug to market.¹⁸ A recent study examined factors that explain variability in the cost of bringing a generic drug to market, including the potential failure of an application.¹⁹ This study found that the total cost for simple products developed in the U.S. could cost \$5 million in capitalized cost (\$2 million in direct costs).²⁰ These estimates can be lower for drugs developed overseas and higher for complex drugs. For some of the most complex drug products, bringing a generic to the market can cost over \$150 million, including the cost of capital and failure.²¹ Without the protections and market exclusivities granted by the Hatch-Waxman Act, brand-name manufacturers would not be willing to risk millions of dollars to develop innovative products if another manufacturer could produce a competitor drug at a fraction of the cost using the

¹⁶ [Pew. FDA Approves More Generic Drugs, but Competition Still Lags. February 2019. Link Verified: June 1, 2022.](#)

¹⁷ [Wouters O., McKee M., and Luyten J. Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018. JAMA. 2020 Mar 3;323\(9\):844-853.](#)

¹⁸ [Federal Trade Commission \(FTC\). Emerging Health Care Issues: Follow-On Biologic Drug Competition: A Federal Trade Commission Report. 2009. June 2009. Link Verified: June 1, 2022.](#)

¹⁹ [Office of the Assistant Secretary for Planning and Evaluation \(ASPE\). Cost of Generic Drug Development and Approval. February 2022. Link Verified: June 1, 2022.](#)

²⁰ [ASPE. Cost of Generic Drug Development and Approval. February 2022. Link Verified: June 1, 2022.](#)

²¹ [ASPE. Cost of Generic Drug Development and Approval. February 2022. Link Verified: June 1, 2022.](#)

brand-name manufacturer's research. Without the abbreviated pathway to approval and a means to challenge patents, generics drug manufacturers would be less willing to incur the costs associated with bringing a second or third version of the drug to market.

As a result of this framework, generic drugs represent more than 90% of drugs dispensed in the United States but account for less than 20% of overall drug costs.²² Additionally, the United States has among the highest saturation and lowest costs of generic products in the world.²³

3. Role and Impact of Generic Drugs

3.1. Impact of Generics on Pharmaceutical Spending

As more generic drugs enter the market, traditional market forces drive generic drug prices down. The first generic to market is often protected by exclusivity for up to 180 days which means that a competitor generic drug may not enter the market during this time. One FDA study found that the cost of the first generic was generally 39% less than the brand-name drug.²⁴ With two competitors, generic prices were 54% lower; with four competitors, generic prices were 79% less; with six or more competitors, generic prices were more than 95% less than the brand prices.²⁵ Combining the competition for all drugs, the median price for generics was 40% of the brand-name drug price.²⁶ Another report found that generic prices were 66% less than the branded drug price 12 months after the generic entered the market, and generic oral prescription drug prices were 74% lower than brand prices two years after entry.²⁷

²² [AAM 2021 U.S. Generic and Biosimilar Medicines Savings Report. October 2021. Link Verified: June 1, 2022.](#)

²³ [The Commonwealth Fund. Paying for Prescription Drugs Around the World: Why Is the U.S. an Outlier? October 2017. Link Verified: June 1, 2022.](#)

²⁴ [FDA. Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices. December 2019. Link Verified: June 1, 2022.](#)

²⁵ [FDA. Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices. December 2019. Link Verified: June 1, 2022.](#)

²⁶ [FDA. Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices. December 2019. Link Verified: June 1, 2022.](#)

²⁷ [IMS Institute. Price Declines after Branded Medicines Lose Exclusivity in the U.S. January 2016. Link Verified: June 1, 2022.](#)

3.2. Generics Utilization is High

In 2020, generics represented 90% of prescriptions filled nationally, yet accounted for only 18.1% of prescription drug spending.²⁸ Due to the difference in price between brand-name and generic drugs, the national substitution of generic drugs for branded drugs yielded a reduction in spending of \$338 billion. In Maryland, the substitution of generic drugs for brand-name drugs is estimated to have reduced the amount spent by \$5.6 billion.²⁹ Based on an internal analysis of the Medical Claims Data Base (MCDB), which contains claims data for approximately 55% of the Maryland fully-insured population, generics represented 84.8% of all prescriptions filled in Maryland, accounting for 18.5% of the total prescription drug spending in CY 2020.³⁰ With full representative data, the Board expects that Maryland’s generic utilization would be comparable to the national trends.

Generic drugs increasingly represent a larger portion of the overall volume of prescription drugs. Over 90% of the national prescriptions written in 2020 were for generic drugs, up from 75% in 2009 and 20% in 1984.³¹ The Office of the Assistant Secretary for Policy and Evaluation (ASPE) found that “generic drug prices are not an important part of the drug cost problem facing the nation.”³²

These trends align with the utilization observed in Maryland, as shown below in Table 1, though Maryland may use a slightly lower proportion of generic drugs based on available data.

²⁸ In conducting its analysis, the Prescription Drug Affordability Board utilized the annual U.S. Generic and Biosimilar Medicines Savings Report, published by the Association for Accessible Medicines, the trade group for the generic drug industry. Where available, the AAM data is supplemented with Maryland data derived from the Medical Claims Data Base (MCDB), which is part of the Maryland All Payer Claims Database (APCD). The Maryland APCD represents about 55% of fully insured Marylanders, excluding ERISA plans and federal employee health benefits (FEHB).

²⁹ [AAM 2021 U.S. Generic and Biosimilar Medicines Savings Report. October 2021. Link Verified: June 1, 2022.](#)

³⁰ Internal analysis based on Medical Claims Data Base (MCDB), which is part of the Maryland All Payer Claims Database (APCD). The Maryland APCD represents about 55% of fully insured Marylanders, excluding ERISA plans and federal employee health benefits (FEHB).

³¹ [AAM 2021 U.S. Generic and Biosimilar Medicines Savings Report. October 2021. Link Verified: June 1, 2022.](#)

³² [ASPE. Issue Brief. Understanding Recent Trends in Generic Drug Prices. January 2016. Link Verified: June 1, 2022.](#)

In aggregate, generics are an important tool for patients to access affordable, high-quality drugs; however, there are exceptions.

4. Findings of Statutory Study of Generics

In this section, the Board addresses the following study questions:

- (i) the prices of generic drugs on a year–over–year basis (section 4.1);
- (ii) the degree to which generic drug prices affect yearly insurance premium changes (section 4.2);
- (iii) annual changes in insurance cost–sharing for generic drugs (section 4.3);
- (iv) the potential for and history of drug shortages (section 4.4);
- (v) the degree to which generic drug prices affect yearly State Medicaid spending (section 4.5); and
- (vi) any other relevant study questions (section 5).

4.1. With Some Exceptions, Generic Drug Prices are Stable on a Year–Over–Year Basis

4.1.1 Aggregate Generic Prices are Generally Stable or Decreasing

In aggregate, the cost per prescription for generic drugs generally remains stable or declines on a year-over-year basis. However, there can be price increases, including dramatic increases, of certain generic drugs.

The Congressional Budget Office (CBO) found that the average net price of a prescription across all prescription drugs declined between 2009 and 2018: from \$57 to \$50 in the Medicare Part D program and from \$63 to \$48 in the Medicaid program. This trend reflects the increased use of lower-cost generic drugs, which was partially offset by rising prices for brand-name drugs. In contrast, the average net price for brand-name prescription drugs increased substantially between 2009 and 2018: from \$149 to \$353 under Medicare Part D and from \$147 to \$218 under Medicaid. The decline in average price for generic drugs in Medicare Part D and Medicaid, coupled with high utilization of generics, drives the overall reduction in the average cost of prescription drugs.³³

³³ [Congressional Budget Office \(CBO\). Prescription Drugs: Spending, Use, and Prices. January 2022. Link Verified: June 1, 2022.](#)

4.1.2 Outlier Drugs Reflect Price Increases

Some generic drugs, however, experience substantial price increases as either percentage increases or overall dollar increases. When the generic drug price is low, even the smallest increase in the dollar amount can result in a large percentage increase; some dollar increases are quite large. In the mid-to-late 2010s, some companies (most infamously Turing Pharmaceuticals, Valeant Pharmaceuticals, and Concordia) purchased off-patent drugs with natural monopolies (often a single manufacturer) and dramatically increased the drug prices.

These outlier drug increases are captured in analyses underpinning the calculation of the NADAC (National Average Drug Acquisition Cost). From July 2013 to 2014, the NADAC increased for half of and decreased for half of all generic drugs.³⁴ The NADAC increased by over 100% for 9% of generic drugs.³⁵ This analysis treats all drugs equally and does not take into account how frequently each drug is used or the impact on overall spending (a 50% drop in a \$2 per pill drug changes spending by more than a 100% increase in a 1 cent per pill drug, assuming the same volume).³⁶

Health General Article § 21-2C-08, the statute establishing a legislative metric to identify generic drugs that may cause affordability issues, expressly recognizes both the percentage increase and overall dollar cost as important drivers. Under the statute, the Board must identify generic drugs with a wholesale acquisition cost (WAC) of more than \$100 per 30-day supply *and* those that increased by 200% or more in an immediately preceding 12-month period.

4.2. Generic Drug Prices Have Minimal Impact on Insurance Premiums

Although Maryland does not currently collect all of the data necessary to enable a comprehensive evaluation of “the degree to which generic prices affect yearly insurance premium changes,” it has collected sufficient ad hoc data from insurance carriers to confirm that in Maryland generic drugs generally exert a deflationary pressure on

³⁴ [Drug Channels. Retail Generic Drug Inflation Reaches New Heights. August 2014. Link Verified: June 1, 2022.](#)

³⁵ [Drug Channels. Retail Generic Drug Inflation Reaches New Heights. August 2014. Link Verified: June 1, 2022.](#)

³⁶ [Drug Channels. Retail Generic Drug Inflation Reaches New Heights. August 2014. Link Verified: June 1, 2022.](#)

insurance premiums, consistent with the national trends. For example, the CBO reports that the average price of a prescription has fallen in both the Medicare Part D and Medicaid programs between 2009 and 2018: from \$57 to \$50 under Medicare Part D and from \$63 to \$48 under Medicaid.³⁷

There are two components to this deflationary pressure from generic drugs. First, the per-prescription price has been declining on average for generic drugs over time, so holding volume constant, there is downward pressure on generic drug spending because the average generic prices are falling. This impact is relatively small because on average, the price declines in generic drugs are relatively small (3% a year). Second, there's the shift from brand to generic prescriptions as brand drugs lose their exclusivity, which has had a significantly greater premium impact. That's because there's such a wide difference in average costs between brand and generic, so even a relatively small shift can lower average drug costs significantly.

However, because generic drugs make up less than 4% of overall health care spending, it is unlikely that marginal changes in generic prices will have a substantive impact on premiums. The actual impact on premiums from these deflationary pressures would require additional data and in-depth analysis. A preliminary internal estimate suggests that an increase of average generic drug prices of over 25% would be needed to result in a 1% increase in premiums.

Maryland may explore collecting additional data to further study this issue.

4.3. Cost-Sharing for Generic Drugs is Stable

In aggregate, patient cost-sharing for generic drugs generally remains stable or decreases on a year-over-year basis, especially compared to brand-name cost-sharing. Industry reports confirm that between 2018 and 2021, the average copay³⁸ for generic drugs

³⁷ [CBO. Prescription Drugs: Spending, Use, and Prices. January 2022 Link Verified: June 1, 2022.](#)

³⁸ Cost-sharing is an umbrella term that includes payments by patients in the form of copayments, coinsurance, and payments towards the deductible. In this report we use the term copay synonymously with cost-sharing rather than exclusively referring to copayments.

changed from \$5.63 to \$6.97 and the average copay for branded drugs changed from \$40.30 to \$55.82.^{39,40}

Figure 1. National Average Copay for Generic Drugs and Brand-Name Drugs, 2017-2020^{41,42,43,44}

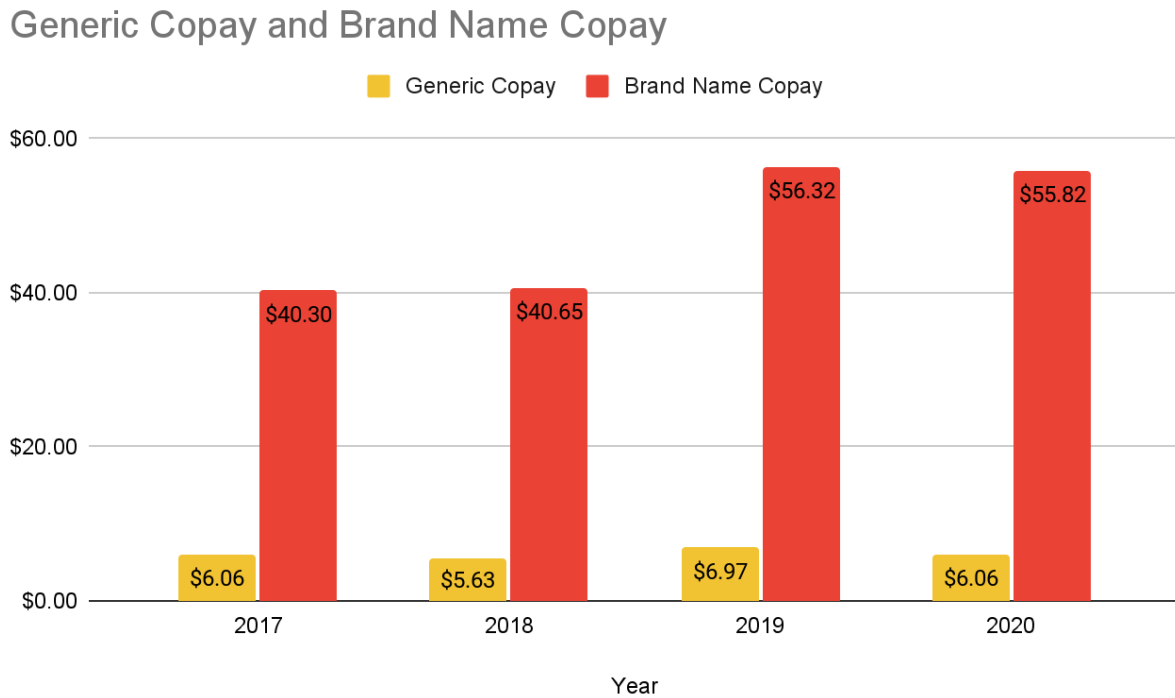


Figure 1 demonstrates that cost sharing for generic drugs remains stable nationwide.

In Maryland, cost sharing is likewise anticipated to remain stable. Because the indicator for generic drugs in the Maryland APCD was overly inclusive and required recalibration,

³⁹ [AAM 2018 U.S. Generic and Biosimilar Medicines Savings Report.2018. Link Verified: June 1, 2022.](#)

⁴⁰ [AAM 2021 U.S. Generic and Biosimilar Medicines Savings Report. October 2021. Link Verified: June 1, 2022.](#)

⁴¹ [AAM 2018 U.S. Generic and Biosimilar Medicines Savings Report.2018. Link Verified: June 1, 2022.](#)

⁴² [AAM 2019 U.S. Generic and Biosimilar Medicines Savings Report. 2019. Link Verified: June 1, 2022.](#)

⁴³ [AAM 2020 U.S. Generic and Biosimilar Medicines Savings Report.2020. Link Verified: June 1, 2022.](#)

⁴⁴ [AAM 2021 U.S. Generic and Biosimilar Medicines Savings Report. October 2021. Link Verified: June 1, 2022.](#)

there was insufficient time for the Board to complete an analysis of Maryland cost-sharing data. However, absent any basis for believing Maryland cost-sharing functions differently, an upcoming review of the Maryland cost-sharing data is expected to confirm the national trend of stability.

4.4. Shortages are an Important Challenge for Maryland Patients and Providers that Requires Further Study

Market failures in the generic drug market sometimes result in drug shortages. Such shortages create access issues and have been problematic in the U.S. for over a decade. While the number of drugs may be limited, every hospital in the country must constantly manage drug shortages of extremely common, cheap, and essential drugs.⁴⁵ Many factors drive these shortages.

Some suggest that market consolidation on the purchasing side (i.e., through hospital group purchasing organizations (GPOs)) has driven margins for generic drugs too low. This leads to consolidation on the manufacturing side, thereby destabilizing the fragile supply chain. With a limited number of manufacturers, any supply chain disruption for a single manufacturer can cause shortages for the entire market.

Additionally, increasing costs for approval and manufacturing of certain generic drugs, coupled with decreasing margins, have caused some manufacturers to marshal their resources and discontinue manufacturing certain generic drugs in order to pursue the production of higher-margin drugs.

4.5. The Effect of Generic Drugs on State Medicaid Spending is Unquantifiable Based on Available Data

It is difficult to assess what reduction, if any, in Medicaid spending is attributable to generic drugs because Medicaid receives rebates through the Medicaid Drug Rebate Program—a program that includes the Medicaid Best Price Rule and incorporates inflation adjustments.⁴⁶ The CBO estimates that amongst the most utilized drugs,

⁴⁵ [60 Minutes. Medical Middlemen: Broken system making it harder for hospitals and patients to get some life-saving drugs. May 2022. Link Verified: June 1, 2022.](#)

⁴⁶ [Baghdadi R. Medicaid Best Price. HA. Health Policy Brief. August 2017. Link Verified: June 1, 2022.](#)

Medicaid receives an average rebate of nearly 80% for branded drugs.⁴⁷ As a result of these unique Medicaid-specific rebates, some brand-name drugs are cheaper than their generic alternatives. Given a cheaper option, cost savings to the Medicaid program may not be attributed to generic drugs based on gross spending.

Table 3. Maryland Medicaid Gross Spend on Pharmacy Benefit Drugs, CY19-CY21⁴⁸

| | Medicaid Fee for Service | Managed Care Organization* |
|-------------|--------------------------|----------------------------|
| CY19 | \$702,197,675 | \$711,502,240 |
| CY20 | \$519,978,647 | \$987,410,100 |
| CY21 | \$572,137,044 | \$1,070,752,084 |

*Based on HealthChoice Financial Monitoring Report (HFMR)

Table 3 shows the gross spending on prescription drugs by the Maryland Medicaid program.

4.6. Physician-Administered Generic Drugs Present Unique Issues that Do Not Reflect the Broader Generic Market

The legislation requires the Board to study physician-administered drugs.⁴⁹ However, the physician-administered generic drug market is difficult to analyze due to limited information, in part because published research focuses on oral dosage form drugs and many physician-administered drugs are injectables. Such drugs are reimbursed as medical benefits subject to different reimbursement practices. Hospital-administered drugs, which are paid for under a hospital benefit, are often subject to drug shortages.

For physician-administered drugs, physicians purchase drug products directly and are reimbursed by insurers when the drugs are administered to a patient. Physicians and hospitals may be members of GPOs to help them negotiate the acquisition price of

⁴⁷ [CBO. A Comparison of Brand-Name Drug Prices Among Selected Federal Programs. February 2021. Link Verified: June 1, 2022.](#)

⁴⁸ Internal analysis of gross spend based on Medicaid claims data.

⁴⁹ The Board has interpreted this task to refer to outpatient physician-administered drugs and not drugs administered to patients during an inpatient hospital stay.

drugs.⁵⁰ The main difference in reimbursement is that medical claims tend to record and pay claims for administered drugs based on the Healthcare Common Procedure Coding System (HCPCS) code instead of the National Drug Code (NDC). The HCPCS codes include both the brand and generic versions of the drugs. Medicaid, on the other hand, receives NDCs from physicians for the purpose of collecting rebates. Generally, HCPCS codes are reimbursed based on the Average Sales Price (ASP) for the code. The Centers for Medicare & Medicaid Services (CMS) releases a single ASP for all brand and generic formulations.

In one study, the HHS Office of the Inspector General (OIG) noted that because of the two-quarter lag in calculating ASP, physicians purchase drugs at a substantial discount for six months after generic entry, but are paid based on the brand price without competition.⁵¹ Despite these concerns, a more recent analysis shows that overall generic entry in Medicare Part B does reduce prices.⁵² Researchers found that the first generic competitor was associated with a 17.0% decrease in drug prices, the second competitor with a 39.5% decrease, the third competitor with a 52.5% decrease, and the fourth and later competitors with a 70.2% decrease.⁵³

5. Issues in the Generics Drug Market

For most dispensed drugs, market competition provides for affordable generic prescription drugs for most patients. The effectiveness of the generics drug market hinges on healthy competition between multiple manufacturers that produce the same generic drug; however, an estimated half of generic drugs are produced by two or fewer manufacturers.⁵⁴ Additionally, the nature of the generics market—a low-margin business where volume is key—drives consolidation and discourages new manufacturers from entering the market. Indeed, most of the issues in the generics market flow from market failures that reduce the pool of competitors.

⁵⁰ [RAND. Prescription Drug Supply Chains: An Overview of Stakeholders and Relationships. October 2021. Link Verified: June 1, 2022.](#)

⁵¹ [HHS Office of the Inspector General. Medicare Payments for Newly Available Generic Drugs. January 2011. Link Verified: June 1, 2022.](#)

⁵² [Dickson S, Kent T. Association of Generic Competition With Price Decreases in Physician-Administered Drugs and Estimated Price Decreases for Biosimilar Competition. JAMA Network Open. November 2021. Link Verified: June 1, 2022.](#)

⁵³ These numbers are based on the ASP which include brand and generic prices. As such, they may underestimate the difference between the generic prices and the pre-entry brand price.

⁵⁴ [Berndt E, Conti R, Murphy S. The Landscape of U.S. Generic Prescription Drug Markets, 2004–16. 2017. NBER Working Paper No. 23640. July 2017. Link Verified: June 1, 2022.](#)

5.1. Dramatic Price Increases for Specific Products

While the generics market is competitive for most generic drugs sold in Maryland, some drugs nonetheless experience extreme price hikes. In the mid-2010s, it was popular for companies to acquire an older, off-patent drug made by a single manufacturer, take advantage of the monopoly, and strategically and dramatically increase the price.

Thus, once-inexpensive generic drugs became more expensive by an order of magnitude. For example, in 2014, Turing Pharmaceuticals increased the price of pyrimethamine (Daraprim) from \$13.50 to \$750 (5456% increase) per tablet; Rodelis Therapeutics increased the price of a bottle of cycloserine from \$500 to \$10,800 (2060% increase); and Valeant Pharmaceuticals raised the price of isoproterenol (Isuprel) and nitroprusside sodium (Nitropress) by 525% and 212%, respectively.^{55, 56}

These actions drew criticism from the public and policymakers alike, prompting policymakers to act. The House Committee on Oversight and Reform opened an investigation into the “staggering price increases for generic drugs.”⁵⁷ In 2017, Maryland lawmakers passed legislation prohibiting drug manufacturers from “price gouging in the sale of an essential off-patent or generic drug,” which was later struck down by the Fourth Circuit Court of Appeals.⁵⁸ Additionally, on occasion, the front-page news coverage and attendant public pressure prompted manufacturer reform.⁵⁹

While these cases likely cost the health system millions of dollars, the drugs involved comprised a negligible percentage of the overall generic market volume and spending: because the drugs served limited patient populations, limited drug volumes were sold. However, for individual patients, the price increases could be catastrophic.

⁵⁵ [Pollack A. Drug Goes From \\$13.50 a Tablet to \\$750, Overnight. NYT. September 2015. Link Verified: June 1, 2022.](#)

⁵⁶ [Cohen M. Policy Options For Increasing Generic Drug Competition Through Importation. Health Affairs. January 2019. Link Verified: June 1, 2022.](#)

⁵⁷ [House Committee on Oversight and Government Reform. Press Release. Cummings and Sanders Investigate Staggering Price Increases for Generic Drugs. October 2014. Link Verified: June 1, 2022.](#)

⁵⁸ [Ass'n for Accessible Medicines v. Frosh, 887 F.3d 664, 674 \(4th Cir. 2018\) \(holding statute directly regulated transactions occurring outside Maryland in violation of the dormant commerce clause\).](#)

⁵⁹ [Pollack A. Big Price Increase for Tuberculosis Drug Is Rescinded. September 2015. Link Verified: June 1, 2022.](#)

5.2. Insufficient Market Competition for Some Products, Including Pricing Fixing for Some Products

Market failures can have implications aside from price increases, and they can exist for generic drugs that remain stable or even decrease in cost. Over half of all generic drugs have two or fewer manufacturers, thereby limiting the impact of market competition.⁶⁰ Fewer manufacturers for a particular drug may increase the risk of price fixing. Recent lawsuits and settlements reveal multiple allegations of price fixing by generic manufacturers. In 2016, 20 states, including Maryland, sued six pharmaceutical companies for price fixing;⁶¹ in 2018, Humana sued nearly 30 generics manufacturers for price fixing;⁶² in 2020, most states, including Maryland, sued 26 generics manufacturers for price-fixing;⁶³ and in 2021, Taro Pharmaceuticals, Sandoz, and Apotex Corporation agreed to pay a total of \$447.2 million to resolve alleged violations of the False Claims Act arising from conspiracies to fix the price of various generic drugs.⁶⁴

5.3. Quality and Safety of the Generic Drug Supply Chain

All FDA-approved generic drugs are deemed to be safe, effective, and of the same quality as their brand-name alternatives. Anecdotal evidence, as well as specific cases, suggest that some quality issues may affect certain generic drugs, especially those produced abroad.

Generic drugs manufactured abroad, especially in China and India, make up an important part of the United States generic drug market. In a sample of 30 generic drug national drug codes (NDCs) out of thousands, the University of Minnesota found that 80% (24 of 30) generic NDCs had finished drug products with foreign or unknown sources.⁶⁵ Further upstream, 90% (27 of 30) of generic drug products had raw materials (Active Pharmaceutical Ingredients (APIs)) that were from foreign or unknown sources, while

⁶⁰ [Berndt E, Conti R, Murphy S. The Landscape of U.S. Generic Prescription Drug Markets, 2004–16. 2017. NBER Working Paper No. 23640. July 2017. Link Verified: June 1, 2022.](#)

⁶¹ [Connecticut v. Aurobindo Pharma., 3:16-cv-02056 \(D.Conn. Dec. 15, 2016\) \(complaint\).](#)

⁶² [Humana Inc. v. Actavis Elizabeth, LLC., 18-cv-3299 \(E.D.Pa. Aug. 3, 2018\) \(complaint\).](#)

⁶³ [Connecticut v. Sandoz, Inc., 3:20-cv-00802 \(D.Conn. June 10, 2020\) \(complaint\).](#)

⁶⁴ [US Department of Justice. Pharmaceutical Companies Pay Over \\$400 Million to Resolve Alleged False Claims Act Liability for Price-Fixing of Generic Drugs. October 2021. Link Verified: June 1, 2022.](#)

⁶⁵ [Schondelmeyer S. Strategic Assessment of the Resilience of the U.S. Drug Supply with Lessons from the Pandemic & Recommendations for Moving Beyond. 2021. Link Verified: June 1, 2022.](#)

only 10% (3 of 30) of APIs were made in the U.S.⁶⁶ These numbers, however, may not be representative of the full generic supply, given the acknowledged difficulty in identifying generic drugs manufactured abroad.

One concern is whether there is sufficient oversight of manufacturing facilities abroad. Reporting and anecdotes suggest that for some generic drugs manufactured abroad, there is not sufficient oversight.⁶⁷ Some journalists hypothesize a correlation between where drugs are made and drug quality.⁶⁸ Proponents of this argument point to two publicized cases: (1) a 2008 incident where 81 people died from adulterated heparin traced back to a Chinese supplier in what has been described as a “deliberate scheme to adulterate a lifesaving medication;”⁶⁹ and (2) the recent news that generic valsartan contains a probable carcinogen.⁷⁰ Similar types of contamination were later found in other drugs.⁷¹ Heavy reliance on generic drugs and raw materials manufactured abroad has also been a target of lawmakers in order to promote supply chain security and ensure access to drugs.⁷²

Unfortunately, there is little comprehensive data concerning the quality and safety of generic drugs manufactured abroad. The issues identified generally represent small samples and anecdotal evidence. While Maryland and the U.S. should always work to improve the quality and safety of drug supplies, nearly all cases demonstrate that generic drugs remain safe and effective methods to access affordable medications.

⁶⁶ [Schondelmeyer S. Strategic Assessment of the Resilience of the U.S. Drug Supply with Lessons from the Pandemic & Recommendations for Moving Beyond. 2021. Link Verified: June 1, 2022.](#)

⁶⁷ [Eban K. Bottle of Lies: The Inside Story of the Generic Drug Boom. May 2019. Link Verified: June 1, 2022.](#)

⁶⁸ [Stockman F. Opinion: Our Drug Supply Is Sick. How Can We Fix It? September 2021. Link Verified: June 1, 2022.](#)

⁶⁹ [Harris G. Heparin Contamination May Have Been Deliberate, F.D.A. Says. NYT. April 2008. Link Verified: June 1, 2022.](#)

⁷⁰ [FDA. FDA Updates and Press Announcements on Angiotensin II Receptor Blocker \(ARB\) Recalls \(Valsartan, Losartan, and Irbesartan\). November 2019. Link Verified: June 1, 2022.](#)

⁷¹ [FDA. Information about Nitrosamine Impurities in Medications. November 2021. Link Verified: June 1, 2022.](#)

⁷² [Woodcock J. Testimony. Safeguarding the Pharmaceutical Supply Chains in a Global Economy. October 2019. Link Verified: June 1, 2022.](#)

5.4. Barriers to Generics Market Entry

Generic drugs ensure access to affordable medications, but generic drugs cannot reduce drug costs if they do not come to market. A societal contract exists in which the government gives branded drugs time-limited market exclusivities; when those exclusivities expire, generics come to market at a dramatically reduced price. Despite this framework, there is a long and storied history of brand-name drug manufacturers working to prevent generic manufacturers from coming to market. For drugs with revenues in billions of dollars per year, extending market exclusivities for any period can be incredibly lucrative.

Entire books have been written about how brand-name manufacturers work to extend their market exclusivities,^{73,74} this issue will be addressed in depth in future reports. Examples of strategies that manufacturers use to maintain their exclusivities include using patent thickets,⁷⁵ evergreening,⁷⁶ abusing special exclusivities such as orphan drug designations,⁷⁷ and abusing Risk Evaluation and Mitigation Strategy (REMS) programs,⁷⁸ among others. Anticompetitive practices to prolong market exclusivities beyond their designated timeframe and keep generics off of the market continue to adversely affect the market and deny patients access to more affordable drugs. Patents and market exclusivities are creatures of federal law and are therefore not likely to be directly addressed in Maryland.

5.5. Generic Drugs are Not Favored on Formularies

Increasingly, insurers and pharmacy benefit managers (“PBMs”) place generic drugs on less-favored (i.e., more expensive) formulary tiers, thereby increasing the cost of the generic drug to the patient. In some cases, the generic drug is on a higher (more

⁷³ Feldman R. *Drugs, Money, & Secret Handshakes: The Unstoppable Growth of Prescription Drug Prices*. 2019.

⁷⁴ Feldman R. *Drug Wars: How Big Pharma Raises Prices & Keeps Generics Off the Market*. 2017.

⁷⁵ [CRS. Drug Pricing and Pharmaceutical Patenting Practices. February 2020. Link Verified: June 1, 2022.](#)

⁷⁶ [CRS. Patent “Evergreening”: Issues in Innovation and Competition. November 2009. Link Verified: June 1, 2022.](#)

⁷⁷ [NPR. FDA Moves To Rein In Drugmakers' Abuse Of Orphan Drug Law. September 2017. Link Verified: June 1, 2022.](#)

⁷⁸ [The Commonwealth Fund. Anticompetitive Efforts to Block Affordable Drugs: A Patient’s Story and Policy Solutions. June 2018. Link Verified: June 1, 2022.](#)

expensive) tier than the higher-cost, brand-name alternative.^{79,80} One reason for the preferential placement of brand-name drugs is the availability of rebates paid by the branded manufacturer to the PBM.

Insurers and PBMs may suggest that such preferential placement only occurs when the net price of the brand-name drug is less than that of the generic alternative. Such an assertion is almost impossible to validate because of data confidentiality agreements. What may be cheaper to an insurer or a PBM may not be cheaper for a patient or the health care system. Studies suggest that significant savings may be realized with an increased utilization of generic drugs.⁸¹ This issue is related to the concept of waste-free formularies, in which more brand-name drugs are placed on the formulary when less expensive generics are available.^{82,83}

6. Concluding Recommendations

Based on the findings above, there are several actions that the Board can take, in conjunction with its State partners, to support a robust and dynamic generic drug market.

6.1. Evaluate policies to identify and address generic drugs that cause affordability challenges

Generic drugs may cause affordability challenges, often due to market failures. The Board can identify generic drugs that cause affordability challenges and implement policies to address such concerns. Section 21-2C-08 of the Health General Article requires the Board to identify generic drugs that have both a high price and a high percentage price increase. Drugs identified through this statutory screen are eligible for selection for a cost review under § 21-2C-09; if a drug is determined to cause an

⁷⁹ [Avalere. Generic Drug Placement on Part D Generic Tiers Declines Again in 2021. March 2021. Link Verified: June 1, 2022.](#)

⁸⁰ [Dusetzina S., Sarpatwari A., and Carrier M. Patient and Payer Incentives to Use Patented Brand-Name Drugs vs Authorized Generic Drugs in Medicare Part D. JAMA Network. October 2021. Link Verified: June 1, 2022.](#)

⁸¹ [ASPE. Savings Available Under Full Generic Substitution of Multiple Source Brand Drugs in Medicare Part D. July 2018. Link Verified: June 1, 2022.](#)

⁸² [The Commonwealth Fund. Reducing Wasteful Spending in Employers' Pharmacy Benefit Plans. August 2019. Link Verified: June 1, 2022.](#)

⁸³ [NASHP. How Waste-Free Formularies Create Savings on Prescription Drugs. June 2020. Link Verified: June 1, 2022.](#)

affordability challenge, it may be subject to policy interventions, including but not limited to an upper payment limit.

The Board, with its Maryland state partners, should continue to identify generic drugs that have created affordability challenges due to high prices or high price increases and research and evaluate policies, such as upper payment limits, to address these challenges.

6.2. Evaluate opportunities to collect additional data to better understand the impact of generic drugs on drug affordability and issues in the drug market

The impact and substance of the analyses in this report are limited by the available data. For example, the available data did not include information from insurers needed to assess the impact of generic drug spending on premiums, nor did it include any Maryland-specific, quantifiable data related to drug shortages.

The Board, with its Maryland state partners, should explore opportunities to collect additional data to better understand issues in the generic market and inform potential policy solutions.

6.3. Explore partnerships with generic manufacturers to promote a secure and affordable generic drug supply chain

Unaffordable generic drugs, drug shortages, and supply chain issues may be addressed through the vehicle of a new business model—the non-profit drug company.^{84,85} To prevent shortages and ensure access to low-cost drugs, states have also begun to partner with such non-profit companies and others, or even develop their own manufacturing capacity.⁸⁶

The Board, with its Maryland state partners, should explore opportunities to partner with generic manufacturers, or other others, to secure a stable, affordable supply of generic prescription drugs.

⁸⁴ [Civica Rx. Link Verified: June 1, 2022.](#)

⁸⁵ [Mark Cuban Cost Plus Drug Company. Link Verified: June 1, 2022.](#)

⁸⁶ [NASHP. California Enacts Law to Produce Generic Prescription Drugs. October 2020. Link Verified: June 1, 2022.](#)

6.4. Evaluate waste-free formularies as a policy to promote savings through generic drugs

Increasingly, insurers and PBMs place generic drugs on less-favored (i.e., more expensive) formulary tiers, which in turn increases the cost of the generic drug to the patient.

The Board, with its Maryland state partners, should evaluate the impact and opportunity of policies, such as waste-free formularies, to promote the uptake of lower-cost generic drugs.

6.5. Explore policies to address drug shortages in Maryland

Drug shortage issues are major challenges and disruptions for Maryland patients and prescribers.

The Board, with its Maryland state partners, should continue to study and quantify the issues around drug shortages and explore policies to address drug shortages in Maryland.

6.6. Explore policies to support a safe, robust supply chain for generic drugs in Maryland

Generics are an essential part of the Maryland prescription drug market.

The Board, with its Maryland state partners, should continue to study and evaluate policies that support a safe, robust supply chain for generic drugs in Maryland.