**Testimony for MD SB 393.pdf**
Uploaded by: Ashlie Van Meter
Position: FAV

**Testimony of Ashlie Van Meter, Senior Director, State Government Affairs at the Association for Accessible Medicines**

**Regarding SB 393, Health Insurance - Prescription Drug Formularies and Coverage for Generic Drugs and Biosimilars**

My name is Ashlie Van Meter. I am the Senior Director of State Government Affairs at the Association for Accessible Medicines (AAM); I submit this testimony on behalf of AAM, the Nation's leading trade association for generic and biosimilar manufacturers. AAM works to preserve patient access to generic and biosimilar medicines, ensure coverage and promote the use of biosimilars, lower patient costs by ensuring appropriate formulary placement for generics and biosimilars, and address the harmful impact rebates have on these important goals.

Improving Patient Access and Savings from Generic and Biosimilar Medicines Generics and biosimilars represent **90% of all prescriptions** filled in the U.S. but **only 13.1%** of prescription drug spending. In 2023, these medicines **generated $445 billion in savings in the U.S**., including **$206 billion in savings** for commercial health insurance plans and patients. On average, the use of generics and biosimilars saved more than **$8 billion per state in 2023**, with annual savings ranging from **$600 million to nearly $38 billion**.[1] **In 2023, generics and biosimilars saved the State of Maryland $1.3 billion**. Although generic drugs and biosimilars provide significant cost savings, patients may not receive the savings because of PBM practices that (1) delay coverage and (2) force patients to pay more than necessary. Policymakers should ensure rapid formulary coverage of new generics and biosimilars and ensure that patients receive the full value of lower-cost medicines.

## Problem: Delays in formulary coverage block patient access to new, lower-cost generics and biosimilars.

According to the U.S. Government Accountability Office, rebates on high-priced brand drugs can be used to block patient access to lower-priced generic or biosimilar medicines. For instance, brand drug manufacturers may threaten to withdraw rebates on a product or group of products if the plan prefers a generic or biosimilar on its formulary. As a result, a first generic - the first approval by FDA of a new generic drug - can face significant, multi-year delays in achieving broad formulary coverage. In fact, it takes up to three years for new generics to achieve coverage on 50% of Part D formularies, despite generic prices up to 95% less than brand prices. Although an average of 50 percent or more of commercial plans typically cover first generics the year after launch, this coverage appears to plateau over time.[2]

PBM formulary decisions to delay coverage of new generics and biosimilars deny patients access to lower-cost generics and biosimilars and create incentives for brand drugs to maintain high prices. For example, PBMs and health plans are increasingly placing generic medicines on non-generic formulary tiers, forcing patients to pay more for affordable drugs. A staggering 60% of generics in Medicare are placed on higher tiers, and from 2011 to 2019, patient costs for these medicines rose by 135%—even as drug prices dropped. And, as we saw with the launch of lower-cost biosimilar versions of Humira®,

[1] Association for Accessible Medicines (September 2024) The US Generic and Biosimilar Medicines Savings Report, https://accessiblemeds.org/resources/blog/2024-savings-report

[2] Association for Accessible Medicines Contributors. (October 2022). Patients Pay More When Generic Drugs Are Placed On Non-Generic Tiers, Even Though Prices for Generics Are Going Down. https://accessiblemeds.org/resources/blog/patients-pay-more-when-generic-drugs-are-placed-non-generic-tiers

PBMs are increasingly slow to cover new generics and biosimilars, even when they offer price discounts of greater than 80%.[3]

**PBMs Block Patient Access to Biosimilar Insulin**

Although biosimilar insulin came to market at a 60% discount compared to the brand, Avalere Health recently found that PBM formulary controls significantly restrict access to biosimilar insulin in Medicare, with the five major payers offering better coverage for the brand while blocking or limiting coverage for the lower cost biosimilar. In fact, Medicare Advantage plans covered the lower-priced biosimilar only 3% of the time.[4]

PBMs Slow Adoption of Lower-Priced Biosimilar versions of Humira IQVIA data reveals commercial health plans and patients missed out on savings up to $6 billion as a result of rebate schemes by pharmacy benefit managers, highlighting PBMs' strategy to protect $2 billion in profits by suppressing adoption of lower-cost, biosimilar versions of Humira. IQVIA found that adalimumab biosimilars offer up to $6 billion in potential savings to the U.S. healthcare system; however, switching all U.S. patients would lead to an estimated 84% decrease in PBM profits. Because the majority of branded adalimumab is dispensed by large specialty pharmacies, a switch would also represent a potential loss of revenue for these businesses that frequently share corporate ownership with PBMs. IQVIA also found that, even when rebates are taken into account, lower wholesale acquisition cost (WAC) biosimilar options have lower net costs for employers and patients.[5]

## Problem: Formulary placement forces patients to pay high prices for generics even as their prices fall.

Despite years of demonstrated savings and price deflation, PBMs continue to make coverage, formulary, and utilization management decisions that require patients to pay more for many generic drugs and biosimilars even as the prices of those medicines have fallen. It is critical that states address PBM tiering practices that increase patient costs for lower-cost medicines. Simple formulary reforms that place lower-cost generic drugs and biosimilars on existing generic and preferred product tiers can level the playing field by prioritizing coverage decisions and by nudging health plans and PBMs towards patient-centric choices. Even when PBMs cover generic and biosimilar medicines, formulary placement can cause confusion and generate unnecessarily high costs to patients. Generic drugs are increasingly moved to formulary tiers with higher patient out-of-pocket costs despite their lower prices. Although generic drug prices have fallen more than $6.4 billion in the past five years, they are often placed on formulary tiers with higher copays. Formulary placement has a direct impact on patient costs. Avalere found that patient spending on generic drugs in Medicare skyrocketed from $8.5 billion in 2011 to $20 billion in 2019. This 135% increase in out-of-pocket spending is directly attributable to higher patient copays and occurred as the average price of generics fell by more than one-third. Nearly two-thirds of Medicare patients were

[3] Biosimilars Council (July 2024) PBM Schemes to Control Biosimilar Humira Are Denying Patients Savings – New Analysis Shows PBM Strategies and Brand 'Product Hopping' Are Suppressing Uptake of Lower Cost Biosimilar Adalimumab, https://biosimilarscouncil.org/news/pbm-schemes-control-biosimilar-humira-denying-patients-savings

[4] Association for Accessible Medicines Contributors. (March 2024). PBMs Continue to Block Patient Access to Lower-Priced Biosimilar Insulin. https://biosimilarscouncil.org/resource/pbms-block-patient-access-lower-priced-biosimilar-insulin

[5] IQVIA, Adalimumab Biosimilar Tracking, prepared for Biosimilars Council: https://biosimilarscouncil.org/wp-content/uploads/2024/04/04022024_IQVIA-Humira-Tracking-Executive-Summary.pdf

also forced to pay full cost for at least one generic in 2020 as more insured patients pay cash to save on their generics, a practice that creates risks for patient safety.[6]

**Problem: While generics and biosimilars have created significant savings, more savings should be available to patients, especially in the area of lower-cost biosimilars.**

An IQVIA study found that had all U.S. patients using Humira been switched to adalimumab biosimilars after they launched in 2023, commercial plans, employers, and patients could have realized additional savings of approximately $6 billion dollars. PBM rebates and fees tied to high brand list prices continue to maintain a stranglehold on coverage decisions, to the detriment of patients. Despite price discounts of greater than 80 percent, adoption of biosimilar versions of Humira has been disappointingly slow, achieving less than two percent market share in their first year on the market. Even when rebates are considered, biosimilar options have lower net costs for employers and patients. IQVIA found that adalimumab biosimilars offer up to $6 billion in potential commercial market savings; however, switching all U.S. patients would lead to an estimated 84 percent decrease in PBM profits. Savings from appropriately tiered generic and biosimilar medicines would limit the need for PBMs and health plans to increase premiums. The vast majority of biosimilar Humira adoption in 2023 was by PBMs that are not reliant on rebate revenue and that prioritize use of lower-priced medicines.

**Solution: Passage of SB 393: Health Insurance - Prescription Drug Formularies and Coverage for Generic Drugs and Biosimilars**

With the passage of SB 393, generics will appropriately be placed on a formulary tier with lower out-of-pocket costs than the brand. This approach requires plan design to optimize the use of generic and biosimilar medicines by creating clarity and consistency in formulary construction. SB 393 will rightfully establish a level playing field between lower-cost medicines and high-cost products that rely on the payment of hidden rebates and fees to PBMs to secure favorable placement on health plan formularies. SB 393 ensures that a transparent model of plan and formulary design will be utilized in an effort to deliver the largest amount of savings to payers and patients without the reliance on questionable PBM rebate practices.

SB 393 would require commercial health insurers to increase (or provide) patient access to lower-cost generic and biosimilar medications when they are brought to market at a lower cost (WAC) than the brand. Additionally, SB 393 provides for a more favorable out-of-pocket cost for the patient with the correct placement of generic and biosimilar medicines. If multiple biosimilars are available, the plan must cover at least one. Requiring PBM's and health plans to cover new generics and at least one biosimilar at launch if the generic/biosimilar has a lower list price than the brand will increase patient access to life-saving medications and will create incentives for brand drugs to reduce their list price to compete with generics and biosimilars. Placing generics on a formulary tier with lower out-of-pocket costs than the brand requires plan design to optimize the use of generic and biosimilar medicines by creating clarity and consistency in formulary construction.

---

[6] Association for Accessible Medicines Contributors. (October 2022). Patients Pay More When Generic Drugs Are Placed On Non-Generic Tiers, Even Though Prices for Generics Are Going Down. https://biosimilarscouncil.org/wp-content/uploads/2024/04/04022024_IQVIA-Humira-Tracking-Executive-Summary.pdf

Without this legislation, generic drugs are being moved to formulary tiers with higher patient out-of-pocket costs in spite of their lower prices. Rapid formulary placement would remove current multi-year delays in achieving broad coverage caused by PBM controls favoring the higher-cost brand drugs with rebates over lower-cost generics and biosimilars. For these important reasons, AAM provides this testimony in support of SB 393, and respectfully requests it is favorably voted out of committee.

**MCHI_FAV_SB 393.pdf**
Uploaded by: Catherine Kirk Robins
Position: FAV

**TESTIMONY IN SUPPORT OF SENATE BILL 393**
Before the Senate Finance Committee
Maryland Citizens Health Initiative
February 5, 2025

Chair Beidle, Vice Chair Hayes, and Members of the Senate Finance Committee;

Prescription drug affordability has been a primary focus of our organization as we seek to fulfill our mission of ensuring that all Marylanders have access to quality affordable health care. Prescription drug prices—largely for brand-name and specialty drugs—serve as a barrier to patient access, drive up insurance premiums, and strain government budgets. Luckily, biosimilar drugs (medicines very close in chemical structure to the biologic brand name product) and generic medications are very often less expensive than the original prescription drug products, increasing access and capping health spending.

Senate Bill 393 aims to expand access to these products and to improve patient awareness of drug coverage on formularies. Currently, biosimilars make up approximately 23% of the biologics market, with this number likely remaining this low due to originator's contracts with insurers and differences in biosimilar formulations.[i] While generic drugs already represent approximately 84% of prescription volume in the US, expanding access will likely lead to further reduction of spending.[ii] When the generic market is functioning as intended, generic competition works very well to reduce spending, which in turn helps patient access.

We respectfully request a favorable report of Senate Bill 393 to further improve Marylanders' access to affordable prescription drugs.

[i] https://www.centerforbiosimilars.com/view/biosimilars-account-for-23-market-share-with-wide-uptake-disparities-across-molecules

[ii] https://aspe.hhs.gov/topics/prescription-drugs-other-medical-products/prescription-drugs-0/incentivizing-generic-biosimilar-product-uptake#:~:text=About%2084%25%20of%20all%20prescription,35%25%20in%20other%20OECD%20nations.

2600 St. Paul Street Baltimore, MD 21218
www.healthcareforall.com
Phone (410)235-9000 Fax (410)235-8963

**SB0393_FAV_MedChi_HI - Pres. Drug Formularies & Co**
Uploaded by: Danna Kauffman
Position: FAV

# MedChi

*The Maryland State Medical Society*
1211 Cathedral Street
Baltimore, MD 21201-5516
410.539.0872
Fax: 410.547.0915
1.800.492.1056
www.medchi.org

Senate Finance Committee
February 5, 2025
Senate Bill 393 – *Health Insurance – Prescription Drug Formularies and Coverage for Generic Drugs and Biosimilars*
**POSITION: SUPPORT**

MedChi, The Maryland State Medical Society, the largest physician organization in Maryland, supports Senate Bill 393. This bill alters transparency requirements related to formularies by:

- Requiring a carrier to post on its website an updated and complete formulary that is easily accessible, including any tiering structure and indicating any restrictions on the manner in which the drug may be obtained.
- Prohibiting a carrier from requiring an individual to create or access an account or enter a policy number to view the formulary.
- Requiring the carrier to clearly indicate which formulary applies to which plan if it offers more than one prescription drug benefit plan.

The bill also requires a carrier that provides coverage for a reference-listed drug (defined in the bill) to provide coverage for the generic or biosimilar drug with more favorable cost sharing if the U.S. Food and Drug Administration approves the reference-listed drug, marketed as a generic, and has a wholesale acquisition cost less than the reference-listed drug on the initial date of marketing for the generic drug.

Consumers are encouraged to research a carrier's insurance coverage prior to picking a plan. However, when carriers require consumers to create an account or enter a policy number to view the formulary, it undermines their ability to select a plan appropriately. In addition, given that carriers manage different levels of prescription drug benefit plans (i.e., plans under ERISA or small group market), it is important to differentiate among plans. For example, the State regulates both the individual and small group market but not ERISA plans. Therefore, it needs to be clear to consumers if different formularies are connected to different plans and not just refer to the "commercial market."

For these reasons, we urge a favorable vote.

**For more information, call:**
Danna L. Kauffman
J. Steven Wise
Andrew G. Vetter
Christine K. Krone
410-244-7000

## 2025 Legislation - MHCC - SB 393 - HI-Prescription

Uploaded by: David Sharp

Position: FAV

MARYLAND Health Care Commission

**Randolph S. Sergent, Esq,** Chairman
**Ben Steffen**, Executive Director

**2025 SESSION**
**POSITION PAPER**

**BILL NO:** **SB 393**

**COMMITTEE:** **Senate Finance Committee**

**POSITION:** **Support**

**TITLE:** **Health Insurance - Prescription Drug Formularies and Coverage for Generic Drugs and Biosimilars**

## BILL ANALYSIS:

*SB 393 - Health Insurance - Prescription Drug Formularies and Coverage for Generic Drugs and Biosimilars* requires health insurers and non-profit health service plans to post on their websites an updated, accurate, and complete prescription drug formulary that is easily accessible to insured members, prospective members, the State, and the public. The bill prohibits the requirement that an individual create or access an account or enter a policy number on the carrier's website to view the posted formulary. Any changes to the formulary must be posted on their website within thirty days of the change, indicating the date of the change, and a description of the change. The bill also requires health insurance carriers to make specific generic drugs and biosimilars available on the formulary without imposing cost-sharing requirements, prior authorization, or step therapy requirements.

## POSITION AND RATIONALE:

The Maryland Health Care Commission (MHCC) supports SB 393, a bill that benefits consumers by requiring transparency of drug formularies and making specific generic drugs and biosimilars available on a formulary without imposing cost-sharing requirements, prior authorization, or step therapy requirements. While the reasons for prescription drug price increases are complicated and varied, rising prescription drug costs may adversely affect patients' health when they cannot afford the medications prescribed to them.

By removing most of the barriers consumers encounter when determining whether a carrier covers a particular prescription drug, this bill ensures that a given prescription

is available, affordable, and timely when care is desperately needed. It also enables consumers to make better-informed decisions for their families when selecting a health insurance carrier based on the prescription benefits.

For the reasons mentioned above, MHCC supports SB 393.

**SB0393 Written Testimony.pdf**
Uploaded by: Jason Rush
Position: FAV

**Statement of Maryland Rural Health Association**

To the Senate Finance Committee

Chairman Pamela Beidle

January 30, 2025

Senate Bill 0393 Health Insurance - Prescription Drug Formularies and Coverage for Generic Drugs and Biosimilars

**POSITION: SUPPORT**

Chair Beidle, Vice Chair Hayes, and members of the Committee, the Maryland Rural Health Association (MRHA) is in SUPPORT of Senate Bill 0393 - Health Insurance - Prescription Drug Formularies and Coverage for Generic Drugs and Biosimilars

MRHA supports this legislation requiring any carrier who provides health benefit plans subject to regulation by the state to post drug formularies and other drug pricing information on their website in an easily accessible manner.

According to research published in the Journal of American Medicine, per capita drug spending in the U.S. is greater than that of any other country and is largely related to brand name drug prices which have been steadily increasing in recent years. A key driver for these high prices is market exclusivity granted to manufacturers by the FDA. After this exclusivity period ends however, generic and biosimilar versions of name brand drugs can be produced and sold at much more reasonable prices. The availability of generic drugs is considered a primary means of reducing drug prices in the U.S.

Obligating greater transparency in prescription drug pricing formularies and eliminating obstacles to access to generic and biosimilar drugs will be of benefit to all Marylanders. Rural communities, which tend to carry a greater financial burden for prescription drug access, stand to be particularly benefited.

MRHA believes this legislation is important to support our rural communities and we urge you to support its passage.

On behalf of the Maryland Rural Health Association,

*Jason Rush, MRHA Legislative and Policy Intern, 314-374-8951*

**DOCS-#238629-v1-SB_393_League_OPPOSE_2025.DOCX.pdf**
Uploaded by: Matthew Celentano
Position: UNF

The League of Life and Health Insurers of Maryland

15 School Street, Suite 200
Annapolis, Maryland 21401
410-269-1554

February 5, 2025

The Honorable Pam Beidle
Chair, Senate Finance Committee
3 East
Miller Senate Office Building
Annapolis, MD 21401

**Senate Bill 393 - Health Insurance - Prescription Drug Formularies and Coverage for Generic Drugs and Biosimilars**

Dear Chair Beidle,

The League of Life and Health Insurers of Maryland, Inc. respectfully opposes ***Senate Bill 393 - Health Insurance - Prescription Drug Formularies and Coverage for Generic Drugs and Biosimilars*** and urges the committee to give the bill an unfavorable report.

Senate Bill 393 proposes instant market access for FDA approved generics and biosimilars that would create confusion for consumers, provide unfair trade advantages for qualifying pharmaceutical manufactures, and diminish the role medical professionals have in designing formularies.

The FDA approval process does not compare drugs under review for efficacy, medical outcomes, or cost effectiveness against other available products or therapies. Health plans use medical evidence and the expertise of physicians, pharmacists and other medical professionals to make these determinations when establishing their formularies.

Formularies are updated frequently, with Maryland law already requiring that the formulary be posted, such that prospective members and enrollees can search and compare formularies. State law also requires that enrollees be provided with notice of an adverse change to a formulary unless there is a safety concern. This is a workable framework that provides certainty to patients, providers, health plans, and purchasers of health insurance.

The FDA Orange Book is a 2,000-page guide of approved drug products with therapeutic equivalence evaluations. The agency provides daily Electronic Orange Book product information for new generic

drug approvals. If Senate Bill 393 becomes law with its "shall immediately" provision, health plans could be required to instantly add all 32,000 FDA-approved generic drugs to their formularies and update formularies daily without determining if a product is even available to Maryland consumers. As you might imagine, automatically adding 32,000 drugs to a formulary, many of which will add no medical benefit, will also have tremendous cost implications.

The bill also restricts practices carriers use to manage utilization. It also provides manufacturers of FDA approved generics or biosimilars with unfair trade advantages with its limitations on prior authorization, step therapy requirements, and coverage limitations. It also would require plans to make generic or biosimilars available to consumers at a lower out-of-pocket cost to an insured than a brand drug based on a comparison of wholesale acquisition costs. Because net costs negotiated between a plan and manufacturer may be lower than the WAC, this requirement could create an unfair market advantage for a higher cost product.

For these reasons, the League urges the committee to give Senate Bill 393 an unfavorable report.

Very truly yours,

Matthew Celentano
Executive Director

cc: Members, Senate Finance Committee

**SB 393 (HB 529) - MIA - LOI - Clean  Final .pdf**
Uploaded by: Marie Grant
Position: INFO

WES MOORE
Governor

ARUNA MILLER
Lt. Governor

MARIE GRANT
Acting Commissioner

JOY Y. HATCHETTE
Deputy Commissioner

DAVID COONEY
Associate Commissioner
Life and Health Unit

Maryland
INSURANCE ADMINISTRATION

200 St. Paul Place, Suite 2700, Baltimore, Maryland 21202
Direct Dial: 410-468-2471 Fax: 410-468-2020
1-800-492-6116 TTY: 1-800-735-2258
www.insurance.maryland.gov

**Date:** **February 5, 2025**

**Bill # / Title:** **Senate Bill 393 - Health Insurance – Health Insurance - Prescription Drug Formularies and Coverage for Generic Drugs and Biosimilars**

**Committee:** **Senate Finance Committee**

**Position:** **Letter of Information**

The Maryland Insurance Administration (MIA) appreciates the opportunity to provide information regarding Senate Bill 393.

Senate Bill 393 mandates that health insurance carriers in Maryland provide transparent and accessible information about their prescription drug formularies online. It also requires carriers to offer generic drugs and biosimilars at more favorable cost-sharing terms than their brand-name counterparts, without imposing additional barriers such as prior authorization or step therapy.

The MIA notes for the Committee certain provisions of SB 393 that could be clarified to improve clarity and enforceability.

The formulary requirements in new § 15-147 of the Insurance Article, created in the bill, apply to carriers defined very broadly as insurers, nonprofit health service plans, HMOs, dental plan organizations and any other person that provides health benefit plans subject to regulation by the State. The bill would benefit from increased clarity if the language were to specify that these formulary requirements would only be applicable if prescription drug coverage was required by the carrier.

In addition, the bill contains a definition of formulary which, as presently drafted, could limit the types of coverage and formulary designs to which the bill applies. The proposal defines "formulary" as a list of prescription drugs that is developed by a carrier's pharmacy and therapeutics committee or other clinical and pharmacy experts, and represents the prescription drugs approved for coverage under a health benefit plan. The reference to "health benefit plan" limits the types of coverage to which the new statute applies.
The bill also contains a number of requirements for insurance carriers which, as written, would need to be further defined to be enforceable. For example, the bill requires carriers to post updated, accurate formularies on their websites that are "easily accessible" to enrollees. It also

requires carriers to "immediately make a generic drug/biosimilar available on a formulary with more favorable cost-sharing," and states that "an entity subject to this section may not impose a restriction on a pharmacy that makes it more difficult for an enrollee to obtain coverage for or access to a generic drug/biosimilar added to a formulary." If the bill is not revised to contain more specific requirements, MIA would further define these terms through regulation.

The bill also requires that changes to a formulary during a plan year be posted on a carrier's website within 30 days after the change. Current law, §15-831(f) of the Insurance Article, requires notice of a change to the formulary be given 30 days before the change is implemented. The MIA recommends adding text to clarify that this new requirement is meant to be an addition to, and not a substitute for, the current requirements. The MIA further recommends that the bill include language indicating that the formulary posted on the website must be accurate, that inaccuracies in the formulary constitute a violation of the Insurance Article, and require carriers to have procedures in place which keep the formularies up-to-date.

Finally, the bill adds provisions to §15-861 of the Maryland Insurance Article which give carriers broad authority to not cover drugs at their own discretion. In particular, new subsection §15-861(g) contains an exception from required coverage if it is no longer medically appropriate or cost effective. The language may conflict with other required coverages in the Insurance Article unless further clarified.

Thank you for the opportunity to provide this letter of information. The MIA is available to provide additional information and assistance to the Committee.