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Senate Bill 3 (Substitute S-1 as passed by the Senate)

Senate Bills 4 and 5 (as passed by the Senate) Sponsor: Senator Darrin Camilleri (S.B. 3)

Senator Veronica Klinefelt (S.B. 4)

Senator Sue Shink (S.B. 5)

Committee: Finance, Insurance, and Consumer Protection

Date Completed: 8-18-25

## **RATIONALE**

Prescription drugs are expensive for Michigan residents, as the average price of prescription drugs in the United States is 2.56 times the price of drugs in peer countries.¹ This may require Michigan residents to choose between necessary medication and essential goods and services or segment pills to stretch the length of time between purchases. According to testimony before the Senate Committee on Finance, Insurance, and Consumer Protection, nearly 1/3rd of Michigan residents have foregone purchasing their medications due to high costs, which may lead to worsening of symptoms, chronic conditions, or other health concerns. These consequences can lead to school and job absences and lost wages, which can further the problem of unaffordability. To make prescription drugs more affordable for Michigan residents, it has been suggested that a Prescription Drug Affordability Board be formed to conduct cost affordability reviews and set upper payment limits for certain drugs deemed unaffordable for patients.

# **CONTENT**

<u>Senate Bill 3 (S-1)</u> would enact the "Prescription Drug Cost and Affordability Review Act" to do the following:

- -- Establish the Board and the Council and prescribe their membership and duties.
- -- Require the Board, in consultation with the Council, to select prescription drug products based on specified criteria and costs and determine whether to conduct cost and affordability reviews for them based on average patient cost share.
- -- Specify the information that the Board could, and would have to, consider when conducting a cost and affordability review for a prescription drug product.
- -- Allow the Board to establish upper payment limits on prescription drug products if it determined that spending on a prescription drug product had or would lead to affordability challenges to health care systems or high out-of-pocket costs for patients in the State.
- -- Allow the Attorney General to investigate a violation of an upper payment limit and commence a civil action accordingly.
- -- Establish the Prescription Drug Affordability Fund for support of the Board.
- -- Require the Board to conduct a one-time study concerning prescription drugs and their costs and report its findings to the Legislature.
- -- Require the Board to provide an annual report to the Legislature detailing specified information related to prescription drug costs.

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<sup>&</sup>lt;sup>1</sup> Mulcahy, Andrew, et al., RAND, *International Prescription Drug Price Comparisons – Current Empirical Estimates and Comparisons with Previous Studies*, January 2021.

- -- Allow the Board to promulgate rules and to enter contracts with third-parties to assist the Board in carrying out its required functions.
- -- Subject the bill's implementation to appropriation.

<u>Senate Bill 4</u> would amend the Insurance Code to require an insurer that offered health insurance policies in the State to comply with upper payment limits established under Senate Bill 3 (S-1).

<u>Senate Bill 5</u> would amend the Social Welfare Act to require the Medical Assistance Program (Medicaid) to comply with upper payment limits established under <u>Senate Bill 3 (S-1)</u>.

# Senate Bill 3 (S-1)

"Prescription drug product" would mean a brand-name drug, a generic drug, biologic, or biosimilar. "Biologic" would mean a drug that is produced or distributed in accordance with a biologics licenses application approved by the United States Food and Drug Administration (FDA). "Biosimilar" would mean a drug that is produced and distributed in accordance with a biologics licenses application approved under 42 USC 262(K), which generally prescribes the requirements for a person applying for licensure of a biological product and specifies the requirements of such a product.

"Generic drug" would mean any of the following:

- -- A retail drug that is marketed or distributed in accordance with an abbreviated new drug application under 21 USC 355.
- -- Any drug sold, licensed, or marketed under the new drug application approved by the FDA of the Federal Food, Drug, and Cosmetic Act that is marketed, sold, or distributed under a different labeler code, product code, trade name, trademark, or packaging than the brand name drug.
- -- A drug that entered the market before 1962 that was not originally marketed under a new drug application.

"Person" would mean an individual and would include a body politic and corporate.

"Prescription drug product purchaser" would mean an entity that purchases and takes ownership of a prescription drug product for resale or providing to patients.

"Third party payer" would mean a health insurer, a State department or agency administering a plan of Medical Assistance under the Social Welfare Act, a person administering a self-funded plan, or a pharmacy benefit manager.

"Health insurer" would mean an insurer authorized under the Insurance Code to deliver, issue, for delivery, or renew in the State a health insurance policy or a health maintenance organization under the Insurance Code. (Generally, a health maintenance organization means a person that, among other things, delivers health insurance services that are medically necessary to enrollees under the terms of its health maintenance contract and is responsible for the availability, accessibility, and quality of the health services provided.)

"Health equity" would mean attaining the highest level of health for all individuals, in which an individual has fair and just opportunity to attain the individual's optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factor that affects access to health care and health outcomes.

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"Manufacturer" would mean an entity that meets any of the following:

- -- Owns the patent to a prescription drug product or enters a lease with another manufacturer to market and distribute a prescription drug product under the entity's own name.
- -- Is the labeled entity, of a generic drug at the point of manufacture and the entity sets or changes the wholesale accusation cost of a brand-name drug that it manufactures or has leased the right to market or the entity sets or changes the wholesale acquisition cost of a generic drug that it manufactures.

"Wholesale acquisition cost" would mean, with respect to a drug or biological, the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.

"Consumer Price Index" (CPI) would mean the United States Consumer Price for all urban consumers as defined and reported by the United States Department of Labor, Bureau of Labor Statistics.

"340B Program entity" would mean a covered entity as that term is defined under the Public Health Service Act. (Generally, the 340B Program requires pharmaceutical manufacturers participating in Medicaid to sell outpatient drugs at discounted prices to healthcare organizations that care for low income or uninsured patients, among other things. (See **BACKGROUND**))

### Prescription Drug Affordability Board

The bill would create the Board as an autonomous entity within the Department of Insurance and Financial Services (DIFS).

The Board would consist of five members appointed by the Governor with advice and consent of the Senate. The members would have to include individuals who had expertise in health care economics, health policy, health equity, clinical medicine, and hospital pharmacy administration. The Governor could not appoint an individual if the individual were affiliated with a manufacturer or a trade association for a manufacturer or otherwise had a personal or financial interest that had the potential to bias or have the appearance of biasing the individual's decisions on the Board.

The Governor would have to appoint two of the first members to one-year terms and three of the first members to two-year terms. After the first appointments, members would be appointed for four-year terms or until a successor was appointed, whichever was later. If a vacancy occurred on the Board, the Governor would have to appoint an individual to fill the vacancy to the balance of the term. The Governor could remove a member of the Board for incompetence, dereliction of duty, malfeasance, misfeasance, or nonfeasance in office, or any other good cause.

The Governor would have to call the first meeting of the Board. At the first meeting, the Board members would have to elect a member as chairperson and other officers as it considered necessary or appropriate. After the first meeting, the Board would have to meet at least quarterly, or more frequently at the call of the chairperson or if requested by at least three members. A majority of the members would constitute a quorum. A majority of the members present and serving would be required for official action unless one or more members recused

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themselves, in that case two thirds of the members present and serving would be required official action of the Board.

The Board would have to comply with the provisions of the Open Meetings Act and the Freedom of Information Act (FOIA). The salaries and other expenses of the Board would be subject to an annual appropriation. Members of the Board would be subject to Public Act 317 of 1968, which governs the conduct of public servants regarding governmental decisions and contracts.

## Prescription Drug Affordability Stakeholder Council

The bill would create the Council within DIFS. The Council would consist of 21 members. Seven of the members would be appointed by the Governor as follows:

- -- One individual representing manufacturers of brand-name drugs.
- -- One individual representing manufacturers of generic drugs.
- -- One individual representing employers.
- -- One individual representing pharmacy benefit managers
- -- One individual representing pharmacists.
- -- One individual representing a mutual insurance company.
- -- One member of the public.

"Brand-name drug" would mean a drug other than an authorized generic that is produced or distributed in accordance with an original new drug application approved under 21 USC 355, which generally specifies the application process and requirements for a person to introduce an original new drug.

The mutual insurance company could not be an entity that directly, or indirectly, through one or more intermediaries controlled, or was controlled by, or was under common control with a managed care organization described below.

The Council also would have to consist of seven members appointed by the Governor from a list of nominees submitted by the Speaker of the House of Representatives. The list of nominees would have to include individuals who represented the following:

- -- A statewide organization that advocated for senior citizens.
- -- A statewide organization that advocated for health care.
- -- A statewide organization that advocated for diversity within communities.
- -- A labor union.
- -- Researchers who specialized in prescription drug products.
- -- The public.

The final seven members would have to be appointed by the Governor from a list of nominees submitted by the Senate Majority Leader. The list of nominees would have to include individuals who represented the following:

- -- Physicians.
- -- Nurses.
- -- Hospitals.
- -- Managed care organizations.
- -- The Department of Technology, Management and Budget.
- -- Clinical Researchers.
- -- The public.

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The managed care organization could not be an entity that directly or indirectly, through one or more intermediaries, controlled, was controlled by, or was under common control with the mutual insurance company described above.

The Governor would have to ensure that the members appointed to the Council had knowledge in at least one of the following areas:

- -- The pharmaceutical business model.
- -- Supply chain business model.
- -- The practice of medicine or clinical training.
- -- Consumer or patient perspectives.
- -- Healthcare cost trends.
- -- Clinical and health services research.

The Governor would have to appoint seven of the first members to one-year terms, seven of the first members to two-year terms, and seven of the first members to three-year terms. After the first appointment, members would be appointed for three-year terms or until a successor was appointed, whichever were later. If a vacancy occurred, the Governor would have to appoint an individual to fill the vacancy for the balance of the term. The Governor could remove a member of the Board for incompetence, dereliction of duty, malfeasance, misfeasance, or nonfeasance in office, or any other good cause.

At the first meeting, the Council would elect a chairperson and other officers as it considered necessary or appropriate. After the first meeting, the Council would have to meet at least quarterly. The Council could meet more frequently at the call of the chairperson or if requested by at least seven members. A majority of the members would constitute a quorum and a majority of the members present and serving would be required for official Council action.

The Council would have to comply with the provisions of the Open Meetings Act and FOIA. Council members would not be entitled to compensation for service on the Council but could be reimbursed for actual and necessary expenses incurred in serving.

#### Cost and Affordability Review

Within 18 months of the bill's effective date, the Board, in consultation with the Council, would have to select at least one prescription drug product based on any of the following criteria:

- -- The prescription drug product was a brand-name drug or biologic that, as adjusted annually for inflation in accordance with the CPI, had a wholesale acquisition cost of at least \$60,000 per year or course of treatment had a wholesale acquisition cost increase of at least \$3,000 in any 12-month period.
- -- The prescription drug product was a biosimilar that had a wholesale acquisition cost that was less than 15% lower than the referenced brand biologic.
- -- The prescription drug product was a prescription drug product that could create affordability challenges for hospitals and health systems in the State and patients, including a prescription drug product needed to address a public health emergency.

Additionally, the Board, in consultation with the Council would choose a prescription drug product based on if the prescription drug product were a generic drug that, adjusted annually for inflation in accordance with the CPI, had a wholesale acquisition cost that was increased by 200% or more during the immediately preceding 12-month period, as determined by the difference between the resulting wholesale acquisition cost and the average wholesale question cost reported over the immediately preceding 12-months and was at least \$100 or more for any of the following:

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- -- A 30 day-supply that lasted a patient a period of 30 consecutive days based on the recommended dosage approved for labeling by the FDA.
- -- A supply that lasted a patient fewer than 30 consecutive days based on the recommended dosage for labeling by the FDA.
- -- One unit of the drug if the labeling approved by the FDA did not recommend a finite dosage.

The Board would not have to identify each prescription drug product that met the criteria listed above. The Board would have to determine whether to conduct a cost and affordability review for each prescription drug product that was selected. The Board would have to consider input from the Council and the average patient cost chare for each prescription drug product.

If the Board conducted a cost affordability review of a prescription drug product, the Board could consider any document or research related to the manufacturer's selection of the introductory price or price increase of the prescription drug product including life cycle management, net average price in the State, market competition, projected revenue, and the estimated cost effectiveness of the prescription drug product. In the review, the Board would have to determine whether the use of a prescription drug product that was fully consistent with the labeling approved by the FDA or standard medical practice for the prescription drug product had led to or would lead to affordability challenges to health care systems in the State or high out-of-pocket costs for patients in the State.

The Board would have to consider any information that a manufacturer chose to provide and all the following factors to the extent possible, in making a determination:

- -- The wholesale acquisition cost for the prescription drug product sold in the State.
- -- The average monetary price concession, discount, or rebate that the manufacturer provided to health insurers and pharmacy benefit managers in the State, expressed as a percent of the wholesale acquisition cost for the prescription drug product under review.
- -- The price at which therapeutic alternatives for the prescription drug product had been sold in the State.
- -- The average monetary price concession, discount, or rebate that the manufacturer provided to health insurers and pharmacy benefit managers in the State or was expected to provide to health insurers and pharmacy benefit managers in the State for therapeutic alternatives.
- -- The cost to health insurers based on patent access consistent with the FDA labeled indications or recognized standard medical practice.
- -- The impact on patient access that resulted from the cost of prescription drug product relative to insurance benefit design.
- -- The current or expected dollar value of drug-specific patient access programs that were supported by the manufacturer.
- -- The relative financial impact to health, medical, or social service costs as could be notified and compared to baseline effects of existing therapeutic alternatives.
- -- The average patient co-pay or other cost-sharing for the prescription drug product in the State.
- -- The impact on hospital access to the prescription drug product, prescription drug product shortage concerns, and the impact on the cost to hospitals purchasing the prescription drug product.
- -- Any other factor established by the Board, by rule.

If the Board considered the estimated cost effectiveness of a prescription drug product, the Board would have to comply with the following:

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- -- The Board could not use a cost-per-quality adjusted life year, or similar measure, to identify a subpopulation for which the prescription drug product would be less cost effective due to severity of illness, age, or preexisting disability.
- -- If the Board used a cost-effectiveness analysis for a prescription drug product that extended an individual's life, the Board would have to use a cost-effectiveness analysis that weighed the value of all additional lifetime gained equally for any individual, no matter the severity of illness, age, or preexisting disability.

### Establishing Upper Payment Limits

If the Board determined that spending on a prescription drug product had led to or would lead to affordability challenges to hospitals and health care systems in the State or high out-of-pocket costs for patients in the State, the Board could establish by rule, an upper payment limit for the prescription drug product. In establishing the upper payment limit, the Board would have to consider the relevant administrative costs related to supplying or stocking the prescription drug product and the impact of an upper payment limit for the prescription drug product on 340B Program entities. The upper payment limit could not include a professional dispensing fee. The upper payment limit could not be established for any prescription drug product that was listed as "currently in shortage" in the drug shortage database maintained by the U.S. Food and Drug Administration. The upper payment limit would take effect on the date prescribed by the Board, by rule, but could not take effect within six months of its establishment.

Except as otherwise provided below, if the Board established an upper payment limit for a prescription drug product intended for use by individuals in Michigan, beginning on the effective date of the limit, a prescription drug purchaser or third party payer could not purchase, bill, or reimburse for the prescription drug product in an amount that exceeded the limit, regardless of whether the prescription drug product was dispensed or distributed in person, by mail, or by other means.

A prescription drug product purchaser or third-party payer could not reimburse any of the following for a prescription drug product in an amount less than an upper payment limit for the prescription drug product:

- -- An independent pharmacy.
- -- A hospital pharmacy.
- -- A hospital.
- -- A behavioral health hospital.
- -- A 340B covered entity.

# **Upper Payment Limit Violations**

Under the bill, the Attorney General could investigate an upper payment limit violation and commence a civil action against a person for appropriate relief, including injunctive relief, for a violation of an upper payment limit. This provision would not prohibit any other sanction against a prescription drug product purchaser or third-party payer as provided by law.

A person aggrieved by a decision of the Board under this bill could request an appeal within 30 days. A hearing and appeal would be subject to the Administrative Procedures Act.

### Prescription Drug Affordability Fund

The bill would create the Prescription Drug Affordability Fund within the State Treasury. The State Treasurer would have to deposit money and other assets from any source into the Fund.

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The State Treasurer would have to direct the investment of money in the Fund and credit interest and earnings from Fund investments to the Fund. Money in the Fund at the close of the fiscal year would remain in the Fund and would not lapse to the General Fund.

The bill would make DIFS the administrator of the Prescription Drug Affordability Fund for audits of the Fund and would require DIFS to spend money from the Fund, on appropriation, only to fund the Board and for costs expended by the DIFS to implement the bill's provisions.

### One-Time Study

The Board would have to conduct a one-time study on the following and report its findings to the Legislature:

- -- The prices of generic drugs on a year-to-year basis.
- -- The degree to which prices of generic drugs affect yearly insurance premium charges.
- -- Annual charges in insurance cost-sharing for generic drugs.
- -- The potential for and history of drug shortages.
- -- The degree to which the prices of generic drugs affected yearly Medicaid spending in Michigan.
- -- The impact of an upper payment limit on 340B Program entities.
- -- Any other issue the Board considered relevant.

# Repeated Report to the Legislature

On or before December 31 of each year, the Board would have to submit a written report to the Legislature that included all the following information:

- -- Price trends for prescription drug products.
- -- The number of prescription drug products that were subject to Board review, including the results of the review and the number and disposition of appeals of Board decisions.
- -- Any recommendations that the Board could have on further legislation to make prescription drug products more affordable in Michigan.

#### Rules and Implementation

The Board could promulgate rules to implement the bill and enter contracts with third parties to assist the Board in carrying out its functions under the Act. The implementation of the Act would be subject to appropriation.

Proposed MCL 500.3406z (S.B. 4) Proposed MCL 400.109o (S.B. 5)

### **PREVIOUS LEGISLATION**

(This section does not provide a comprehensive account of previous legislative efforts on this subject matter.)

Senate Bills 3 through 5 are similar to Senate Bills 483 through 485 of the 2023-2024 Legislative Session. Senate Bills 483 through 485 passed the Senate and were referred to the House Committee on Insurance and Financial Services but received no further action.

### **BACKGROUND**

Upper payment limits were established in the early 1980's when Medicare and Medicaid payments were de-linked and states were given more flexibility to design their own payment

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types for Medicaid.<sup>2</sup> A state's upper payment limit was often set based on an estimate of what would have been paid for the same service under Medicare payment principles. Then, the state would make supplemental payments up to the difference between fee-for-service payments (the payment to a doctor or other healthcare provider for services rendered) and the upper payment limit. In the case of an upper payment limit applied to pharmaceuticals, the upper payment limit is not a price control and does not affect a manufacturer's list prices or the ability to offer price concessions per standard business practice.<sup>3</sup>

The 340B drug pricing program allows covered safety net hospitals and other community care organizations to access certain outpatient prescription drugs at discounted prices.<sup>4</sup> The program has existed under Federal law since 1992 and does not use any State taxpayer dollars. Several hospitals, including cancer hospitals, children's hospitals, hospitals with a disproportionate share of Medicaid patients, rural referral centers, and sole community hospitals have access to the 340B drug pricing program. The program supports community health needs, including supporting service lines such as obstetrics or inpatient psychiatric care, creating financial assistance programs for low-income patients, funding operating mobile health clinics, and providing low-cost access to prescription drugs.

#### **ARGUMENTS**

(Please note: The arguments contained in this analysis originate from sources outside the Senate Fiscal Agency. The Senate Fiscal Agency neither supports nor opposes legislation.)

### **Supporting Argument**

According to testimony before the Senate Committee on Finance, Insurance, and Consumer Protection, high prescription drug costs disproportionately affect older adults, with 40% taking five or more prescriptions and nearly 20% taking 10 or more prescriptions. Additionally, 75% of Michigan residents aged 50 and older report taking prescription medications on a regular basis.<sup>5</sup> Fifty-seven percent of Michigan adults 50 and older are concerned they will not be able to afford prescription drugs over the next few years for themselves or their families, and 58% cite not filling a prescription because of cost.<sup>6</sup> Between July 2021 and July 2022, list prices on 1,216 prescription drug products rose an average of 31.6%, faster than the 8.5% inflation rate during that period.<sup>7</sup> Adults 50 or older make up 20% of Michigan's population.<sup>8</sup> These costs disproportionately affect that 20% of the State, and so implementing an affordability board to introduce upper payment limits on prescription drugs would benefit a significant portion of the State.

# Supporting Argument

According to testimony, drug prices do not reflect their actual cost of development, manufacturing, and distribution. Companies may set prices based on non-market factors such as political views and overinflate their contributions to the research and development (R&D) of new drugs. Firstly, in 2015, U.S. Senators Ron Wyden and Chuck Grassley led an investigation into the price of a Hepatitis C medication called Sofosbuvir. The Senators discovered a color-coded chart describing factors used to decide the final list price of

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<sup>&</sup>lt;sup>2</sup> Medicaid and CHIP Payment and Access Commission, *Upper Payment Limit Supplemental Payments*, November 2021.

<sup>&</sup>lt;sup>3</sup> Jane Horvath, Maryland Prescription Drug Affordability Board, *State Prescription Drug Upper Payment Limits Explained*, March 22, 2011.

<sup>&</sup>lt;sup>4</sup> Michigan Health and Hospital Association, 340B Drug Discount Program, 2023.

<sup>&</sup>lt;sup>5</sup> American Association of Retired Persons, *2022 Michigan Survey on Prescription Drugs*, November 2022.

<sup>&</sup>lt;sup>6</sup> *Id*.

<sup>&</sup>lt;sup>7</sup> Department of Health and Human Services, Assistant Secretary for Planning and Evaluation, *Changes in the List Prices of Prescription Drugs, 2017-2023*, October 2023.

<sup>&</sup>lt;sup>8</sup> "Population Trends", Michigan Department of Health and Human Services. Retrieved 8-14-25

Sofosbuvir, including the opinions of lawmakers, patient advocate statements, views of insurance companies, views of physicians, and views of other key stakeholders. These criteria are political in nature and not driven by market factors such as the cost of the drug's production or the demand for the drug.

Secondly, pharmaceutical companies claim R&D costs as high as \$3.0 billion per year, yet reviews of pharmaceutical research from 2000 to 2018 indicate that the mean for developing a drug was \$172.7 million in real costs. If drug development failures and capital costs are accounted for, the study indicates that the average increases to \$879.3 million. In Finally, from 2012 to 2021, the 14 largest pharmaceutical companies in the world spent more than \$740.0 billion on stock buybacks while spending only \$640.0 billion on R&D. In An affordability board would consider the real costs of developing drugs instead of the additional non-market costs that pharmaceutical manufacturers may use now and so the bill should be passed.

### **Opposing Argument**

Implementing an affordability board has not been shown to lower costs in other states and would harm access to essential pharmaceuticals. On July 1, 2019, Maryland implemented the country's first affordability board with the goal of lowering prescription drug costs for patients; 12 however, since then, affordability boards have created numerous problems. Firstly, they may act in ways that reduce patient access to needed drugs if a pharmaceutical company is prevented from stocking a drug because it cannot afford the upper payment limit. Affordability boards are made up of unelected members who set upper payment limits that don't necessarily reduce patient costs and could be applied to all purchases in the State. One survey of national and regional health plan payers indicates that 77% of health plan payers believe upper payment limits would disrupt patient access to prescription drugs due to coverage changes, tiering adjustments, increased cost-sharing, or supply chain complications, including a potential refusal from pharmacies to stock medicines with upper payment limits. 13

Secondly, affordability boards setting upper payment limits disincentivize biopharmaceutical manufacturers from developing new medicines. When governments set prices on medicines, R&D investment and innovation among biopharmaceutical manufacturers declines. Research performed by private pharmaceutical companies is important to developing drugs that reduce the need for costlier care later. Finally, implementing an affordability board would not affect the insurers and pharmacy benefit managers (PBMs) who may also be responsible for making the price of drugs unaffordable for patients at the counter. Out-of-pocket costs continue to rise, even as rebates and discounts from pharmaceutical manufacturers totaled more than \$356.0 billion in 2024. For these reasons, a Michigan-based affordability board likely would not lower patient costs and could harm access to essential pharmaceuticals. Instead, a more effective solution would be to transition rebates and discounts given to insurers and PBMs by manufacturers to actual lower costs for patients at the counter.

**Response:** The implementation of an upper payment limit would not likely affect drug distribution in Michigan. Drugs are sold through many wholesalers who do business across the United States, which would make restricting the availability of a drug only in one state difficult. Additionally, pharmaceutical manufacturers already sell the same drug to different

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<sup>&</sup>lt;sup>9</sup> Sertkaya, Aylin, PhD, et al, JAMA Network, *Costs of Drug Development and Research and Development Intensity in the US, 2000-2018*, June 2024.

<sup>10</sup> *Id*.

<sup>&</sup>lt;sup>11</sup> Lazonick, William and Tulum, Oner, Institute for New Economic Thinking, *Sick with "Shareholder Value": US Pharma's Financialized Business Model During the Pandemic*, December 2022.

<sup>&</sup>lt;sup>12</sup> Maryland General Assembly, *HB 0768 of 2019*, February 2020.

<sup>&</sup>lt;sup>13</sup> Partnership to Fight Chronic Disease, *Payer Perspectives Confirm UPLs Will Likely Raise Costs and Hinder Patient Access to Medicines*, March 2025.

<sup>&</sup>lt;sup>14</sup> Joe Kennedy, Information Technology & Innovation Foundation, *The Link Between Drug Prices and Research on the Next Generation of Cures*, September 2019.

stakeholders at different negotiated discounts and rebates with the goal of remaining competitive and expanding their market shares. Therefore, manufacturers would be equipped to sell drugs at different rates to stakeholders located within Michigan if Michigan implemented an upper payment limit.

## **Opposing Argument**

The bills would negatively affect a pharmacy's ability to dispense drugs with upper payment limits. Currently, many health plans reimburse pharmacists for the cost of purchasing medication and also pay a professional dispensing fee, which generally covers the overhead costs that pharmacies incur in stocking and dispensing a drug. The bills do not consider the payment of professional dispensing fees, which could lead to pharmacies losing money when distributing drugs with upper payment limits. For this reason, the bills should not be passed unless they include a provision that would allow any drug with an upper payment limit to have a professional dispensing fee determined by the Department of Health and Human Services for the Medicaid program.

### **Opposing Argument**

An upper payment limit could create access issues to affected drugs because of the limited scope of Michigan's enforcement authority. Many group purchasing organizations, wholesalers, and manufacturers are national companies, and as a result, many wholesalers purchase drugs out of state. As out-of-state transactions are outside of Michigan's enforcement authority, an upper payment limit could not be enforced. This could lead to a situation in which a wholesaler could not charge a price for a drug that was profitable at Michigan's upper payment limit, and so a dispenser would have to buy at higher, out-of-state prices to stock the drug; however, the dispenser could only be compensated to the upper payment limit for the drug, resulting in a net loss for the dispenser. Ultimately, dispensers could forego these losses by refusing to supply drugs with upper payment limits.

Further, an upper payment limit in Michigan could promote the creation of an unauthorized, legal market (termed a 'gray' market) in which drugs with upper payment limits are sold through alternative channels for a higher profit. Bad actors could buy a legitimate drug with an upper payment limit at reduced prices within Michigan, transport the drug out of state, then sell the drug at below market price in that state and take the difference as profit. Depending on the volume of transactions happening for this purpose, this could lead to supply issues within Michigan for drugs with an upper payment limit. In a case where Michigan faced supply issues on these drugs due to the development of a gray market, Michigan residents could turn to purchasing illegitimate drugs on a black market at more affordable prices. Therefore, the bills could create access issues for beneficial prescription drugs and so should not be passed.

# **Opposing Argument**

Affordability boards have not been able to make drugs more affordable for patients in states where they are implemented and so represent a waste of public resources. In states that currently have affordability boards, their startup costs have reached \$750,000. According to testimony before the Maryland General Assembly, the first state to implement an affordability board, the board's operating expenses for 2024 totaled over \$1.4 million. Despite these resources spent on affordability boards, testimony indicates that efforts in those states have not resulted in any cost savings to patients. The State should not implement an affordability board that has no proof of efficacy and could cost a significant sum of money.

**Response:** Opposition from pharmaceutical companies is one of the reasons that upper payment limits have not yet been implemented in the United States and therefore why

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<sup>&</sup>lt;sup>15</sup> Peters, Michiel, Global Coalition on Aging, "Concerns Regarding the Impact of Expanding the State Drug Affordability Board on Marylanders & Innovation", February 2025.

affordability boards have not yet achieved cost savings for patients. In March 2024, Amgen, a biopharmaceutical manufacturer, filed a lawsuit against the State of Colorado arguing that establishing an affordability board was unconstitutional. Prior to this lawsuit, Colorado's affordability board had reviewed five drugs for affordability and found that three of the five - Enbrel, Stelara, and Cosentyx - were unaffordable for Colorado residents. After this review, Colorado's affordability board worked toward setting an upper payment limit for Enbrel, an autoimmune disorder drug manufactured by Amgen. On March 28, 2025, Colorado's Federal district court dismissed Amgen's lawsuit, stating that the company did not have standing because it could not effectively establish that its profits would be reduced by the proposed upper payment limit. While no upper payment limit has yet been established in the United States, Colorado's upper payment limit on Enbrel would be the first if implemented. It is because of efforts like this lawsuit that upper payment limits have not been implemented and savings for patients have not been achieved in the United States.

Legislative Analyst: Nathan Leaman

### **FISCAL IMPACT**

### Senate Bill 3 (S-1)

The bill would have a significant negative fiscal impact on State government and no fiscal impact on local units of government.

Under the bill, the salaries and expenses of the five Board members would be paid by an annual appropriation to DIFS. If the Board members were to receive a salary similar to that of the members of the Public Service Commission, these expenditures could total approximately \$750,000; however, this figure is an approximation as the expense needs of the Board are unknown at this time.

Members of the Council would not receive a salary but would be reimbursed for actual and incurred expenses. Typical costs for an advisory board can range from \$10,000 to \$200,000 per year, depending on member expenses and activities.

Additionally, the work of the Board would require an ongoing appropriation to carry out its responsibilities under the bill. The Department estimates that full costs for the Board, including approximately 3.0 FTEs and administrative expenses, would range from \$4.0 million to \$5.0 million per year; however, it should be noted that this estimate could vary significantly from actual costs due to the uncertainty of contracting with third-party entities for certain required activities. Necessary expenditures under the bill would include data analysis and legal resources.

These funds would be appropriated to the Prescription Drug Affordability Fund. The bill would allow for deposits into the Fund from any source. The Department of Treasury would experience minor administrative costs to create and administer the Fund. The costs would be minimal and within current appropriations.

Based on the cost of similar studies and reports, it is likely that approximately \$200,000 to \$500,000 would be required to complete the one-time study outlined in the bill.

The bill would have a minor fiscal impact on the Department of the Attorney General. The Department could devote staff resources to investigating violations or commencing civil action against individuals who violate the bill. This would be unlikely to require additional staffing for the Department and would instead come from existing staff within the Civil Division of the Department.

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### **Senate Bill 4**

The bill would have a minor fiscal impact on the Department of the Attorney General and DIFS.

The Department of Attorney General could devote staff resources to commence civil action against individuals who violate the bill. This is unlikely to require additional staffing for the Department and would instead come from existing staff within the Civil Division of the Department.

The Department of Insurance and Financial Services also could incur some costs related to identifying or investigating insurers who violated the bill, separate from actions taken by the Attorney General. Depending on the number of complaints or violations, additional appropriations could be required to ensure compliance with the bill and any price limits set by the Board; however, these costs likely would be covered by existing departmental resources.

# **Senate Bill 5**

The bill would have an uncertain fiscal impact on the Department of Health and Human Services. If the board established upper payment limits on drugs purchased, billed, or reimbursed for directly by the medical assistance program (Medicaid), there could be a reduction in prescription drug-related expenditures. Since it is not known what drugs could be subject to this requirement as well as how those drugs would interact with the single Medicaid formulary and negotiated prescription drug rebates, the fiscal impact is uncertain. The fiscal impact is contingent upon which drugs were selected by the Board, the price of the drug net of any rebates, and the interaction of the upper payment limit with Federal law governing the Medicaid program's coverage of prescription drugs.

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This analysis was prepared by nonpartisan Senate staff for use by the Senate in its deliberations and does not constitute an official statement of legislative intent.