Senate Fiscal Agency
P.O. Box 30036
Lansing, Michigan 48909-7536

BILL ANALYSIS

Telephone: (517) 373-5383
Fax: (517) 373-1986

Senate Bills 3 through 5 (as introduced 1-8-25)
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

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INTRODUCTION

Senate Bill 3 would create the Prescription Drug Affordability Board (Board) and the Prescription Drug Affordability Stakeholder Council (Council). The Board would have to select prescription drug products based on specified criteria and determine whether to conduct cost and affordability reviews for those products based on their average cost to patients. Upon review, the Board could decide to establish an upper payment limit on a prescription drug product, which is a cap on the amount that a prescription drug purchaser or payer could pay for the product. The bill also would allow the Attorney General to pursue civil actions for a violation of an upper payment limit and subject the bills' provisions to appropriation. The other two bills would require insurers in the State and the Healthy Michigan Plan to comply with upper payment limits on prescription drug products.

Senate Bill 4 and Senate Bill 5 are tie-barred to Senate bill 3.

BRIEF FISCAL IMPACT

The bills would have a significant fiscal impact on State government and no fiscal impact on local units of government. The creation of the Board under the Department of Insurance and Financial Services (DIFS) would require significant appropriations estimated at about $4.0 to $5.0 million per year, including approximately 3.0 Full-Time Equivalents (FTEs). The Department of Attorney General, DIFS, and the Department of Treasury each would incur minor ongoing costs due to administrative and regulatory activities required under bill; however, these activities likely would not require any significant increase in appropriations. The bills would have an indeterminate fiscal impact on the Department of Health and Human Services (DHHS), dependent on the effects of prescription drug prices and reimbursements on Medicaid expenditures.

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

Legislative Analyst: Nathan Leaman
Fiscal Analyst: John P. Maxwell
Elizabeth Raczkowski

CONTENT

Senate Bill 3 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.**
- **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.**

Senate Bill 4 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.

Senate Bill 5 would amend the Social Welfare Act to require the Medical Assistance Program (Medicaid) to comply with upper payment limits established under Senate Bill 3.

Senate Bill 3 is described in greater detail below.

Senate Bill 3

"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.

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

-- Owns the patent to a prescription drug product or enters into 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 Index for all urban consumers as defined and reported by the United States Department of Labor, Bureau of Labor Statistics.

"340B Program entity" would mean an entity authorized to participate in the Federal 340B Program 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 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, and clinical medicine. 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 also could not appoint a registered lobbyist in the State.

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

The Board would have to comply with the Open Meetings Act and the Freedom of Information Act (FOIA). The salaries and other expenses of the Board would be subject to 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.

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 was 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 Council 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 action of the Council.

The Council would have to comply with 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 or 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 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, could 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 acquisition cost reported over the immediately preceding 12-months and was at least $100 or more for any of the following:

-- 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 selected prescription drug product with input from the Council and consideration of 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.
-- 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:

-- 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 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 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 an independent pharmacy licensed under Article 15 (Occupations) of the Public Health Code for

a prescription drug product in an amount less than an upper payment limit for the prescription drug product.

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 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. 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 spent 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 State Medicaid spending.
-- The impact of an upper payment limit on 340B Program entities.
-- Any other issue the Board considered relevant.

Annual Report to the Legislature

On or before December 31 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.

PREVIOUS LEGISLATION

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

Senate Bills 3 through 5 are respectively similar to Senate Bills 483 through 485 of the 2023-2024 Legislative Session. The bills 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 types for Medicaid.[1] 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.[2]

The 340B drug pricing program allows covered safety net hospitals and other community care organizations to access certain outpatient prescription drugs at discounted prices.[3] 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.

FISCAL IMPACT

Senate Bill 3

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.

[1] Medicaid and CHIP Payment and Access Commission, *Upper Payment Limit Supplemental Payments*, November 2021.
[2] Jane Horvath, Maryland Prescription Drug Affordability Board, State Prescription Drug Upper Payment Limits Explained, March 22, 2011.
[3] Michigan Health and Hospital Association, *340B Drug Discount Program*, 2023.

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.

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 DHHS. 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 would depend on 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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