Health-General § 21-2C-09(c)
2025 Annual Report

Maryland Prescription Drug Affordability Board
December 31, 2025

MARYLAND
Prescription Drug Affordability Board

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Board Chair

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MARYLAND
Prescription Drug Affordability Board

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https://pdab.maryland.gov/index.html

INTRODUCTION

Section 21-2C-09(c) of the Health-General Article, Annotated Code of Maryland, directs the Maryland Prescription Drug Affordability Board (Board) to submit an annual report on or before December 31 that includes: (1) price trends for prescription drug products; (2) the number of prescription drug products studied by the Board in a Cost Review Study and the results of those studies; and (3) any recommendations the Board may have on further legislation needed to make prescription drug products more affordable in the State.

PRICE TRENDS FOR PRESCRIPTION DRUG PRODUCTS

National:

Overall U.S. pharmaceutical expenditures in 2024 grew 10.2% compared to 2023, totaling $805.9 billion.[1] This increase was largely driven by a 7.9% increase in utilization and a 2.5% increase in new drugs, while prices had a slight decrease of 0.2%.[2] The top drugs for overall expenditures in 2024, in order, are semaglutide (e.g., Ozempic, Wegovy), tirzepatide (Zepbound, Mounjaro), adalimumab (e.g., Humira and biosimilars), apixaban (Eliquis), and empagliflozin (Jardiance).[3]

At net prices, the U.S. market grew 11.4% in 2024, representing a 4.9% increase from 2023.[4] While net price growth was flat, increased use of medicines with clinical benefits drove the acceleration in spending.[5]

In total, net medicine spending increased by 11.4%, or $50 billion, from $437 billion in 2023 to $487 billion in 2024.[6] Most of the growth was driven by increased sales for 31 products, each of which contributed over $500 million in growth to an aggregate of $50 billion in increased sales.[7] High-growth products contributed $14 billion and new brands contributed $7 billion in growth.[8] Losses of exclusivity offset the growth by $19 billion.[9] Low to moderate growth of thousands of older and generic products between 2023 and 2024 led to a collective decline of $1 billion.[10]

2024 drug expenditures in nonfederal hospitals were $39 billion, representing a 4.9% increase.[11] New products, price, and volume each contributed modestly to this growth in spending.[12] 2024 drug expenditures in nonfederal clinics were $158.2 billion, representing a 14.4% increase.[13] This growth was driven by increased utilization, with new products providing a small contribution, while prices remained relatively flat.[14] Overall prescription drug spending for 2025 is projected to rise by 9% to 11% compared to 2024.[15] Prescription drug spending in hospitals is

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[1] https://pubmed.ncbi.nlm.nih.gov/40263109/
[2] *Id.*
[3] *Id.*
[4] https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/understanding-the-use-of-medicines-in-the-us-2025
[5] *Id.*
[6] *Id.*
[7] *Id.*
[8] *Id.*
[9] *Id.*
[10] *Id.*
[11] https://pubmed.ncbi.nlm.nih.gov/40263109/
[12] *Id.*
[13] *Id.*
[14] *Id.*
[15] *Id.*

anticipated to increase from 2% to 4%, while spending in clinics is anticipated to increase by 11% to 13%, compared to 2024.[16]

Based on defined daily doses, the use of prescription medicines in the U.S. in 2024 reached 215 billion days of therapy.[17] While prescription medicine use grew 14% over the last five years, the rate of growth in 2024 slowed to 1.7%.[18] This was largely due to slowing growth in the use of prescription drugs dispensed from retail pharmacies, as retail drugs represent 83% of U.S. medicine use.[19]

Significant barriers to medicine access persist: patients do not fill over half of new prescriptions for novel medicines due to benefit design and high costs.[20] Across all payers, 27% of new written prescriptions go unfilled due to payer rejections and patient abandonment.[21] The rate of rejection among all payers is 16%.[22] The rate of unfilled prescriptions is 34% in Medicaid, 24% in Medicare, and 28% in commercial insurance.[23] "Payer rejections may be driven by formulary decisions, failure to satisfy prior authorization requirements, refilling too soon or exceeding volume limits, but nearly half of those rejections are overcome either by the patient switching to a secondary insurer, paying cash, or adding a coupon."[24]

Medicine use among Medicare beneficiaries is at a record high.[25] However, some Medicare patients have experienced lower out-of-pocket costs due to Medicare Part D redesign and $35 caps of one-month supplies of insulin under the Inflation Reduction Act.[26] Due to the elimination of patient cost-sharing in the catastrophic phase, fewer Medicare patients paid greater than $3,500 for prescriptions in 2024, and more patients paid between $2,000 and $3,500 for total annual prescription out-of-pocket costs.[27] The reduction in patients above $3,500 annual spend was the main driver of high-cost Medicare patient out-of-pocket aggregate costs decreasing from $7 billion in 2023 to $6.5 billion in 2024.[28]

From 2024 to 2029, total net spending on medicines is expected to increase by $116 billion "as volume growth drivers and adoption of innovation will be partly offset by drivers of lower

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[16] *Id.*
[17] https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/understanding-the-use-of-medicines-in-the-us-2025
[18] *Id.*
[19] *Id.*
[20] *Id.*
[21] *Id.*
[22] *Id.*
[23] *Id.*
[24] *Id.*
[25] *Id.*
[26] *Id.*
[27] *Id.*
[28] *Id.*

prices, including patent expiries and the effects of legislation."[29] Medicine spending is expected to grow by 5-8% over the next five years based on list price and by 3-6% after discounts and rebates are considered.[30] An average of 50-55 new medicine launches per year is expected over the next five years, taking into account oncology drugs, specialty drugs, orphan drugs, and additional therapies in the diabetes, obesity, and neurology markets.[31]

In 2024, FDA-approved generic and biosimilar medicines created $467 billion in savings for patients and the U.S. healthcare system.[32] Over the last ten years, savings due to generics and biosimilars reached $3.4 trillion.[33]

State:

PDAB staff is continuing to analyze pricing data that recently became available for prescription drug products across Maryland market segments. Many of the trends observed nationally also apply to Maryland. The Board may publish a supplemental report focused on Maryland data.

In 2026, the Board will publish a report on the 340B Drug Program as it relates to Maryland. Staff has been monitoring changes to the 340B Program throughout 2025 and will report its findings in the upcoming report.

[29] *Id.*
[30] *Id.*
[31] *Id.*
[32] https://aspe.hhs.gov/sites/default/files/documents/2d5c0a194c180b52d1c760d3bb09f70a/Biosimilars%20Final%20Report_250825_v508.pdf
[33] *Id.*

KEY 2025 MARYLAND PRESCRIPTION DRUG AFFORDABILITY BOARD ACTIONS

Regulatory Update:

The Board published regulations establishing the Cost Review Study Process as COMAR 14.01.04 at the end of 2023, and began to implement its first Cost Review Study in early 2024.

Through the end of 2024 and beginning of 2025, the Board worked on updating its regulations regarding the Cost Review Study Process to account for the Policy Review Process outlined in the Upper Payment Limit Action Plan, which was approved by the Legislative Policy Committee in October 2024. Among other provisions, the amendments to the Cost Review regulations included technical corrections and established procedures for a non-final preliminary determination step in which the Board may determine whether the use of the prescription drug product has led or will lead to affordability challenges to the State health care system or high out-of-pocket costs for patients. The amendments also provided an opportunity for public comment. The Board approved these regulations as final actions in January 2025. *See* COMAR 14.01.04.05.

In March 2025, the Board approved amendments to COMAR 14.01.01.01, a new regulation (COMAR 14.01.01.06), and a new chapter of regulations (COMAR 14.01.05 Policy Review, Final Action, Upper Payment Limits). These went into effect in April 2025.

Over 2025, the Board implemented the Cost Review Study process and Policy Review process in accordance with these regulations.

Overview of Cost Review Study Process:

The Cost Review Study Process, as outlined in the Maryland Code of Regulations ("COMAR") 14.01.01, is a tool for the Board to study specific drugs to understand if each drug causes an affordability challenge for Maryland patients or for the healthcare system throughout the State of Maryland. The Board "determine[s] whether use of the prescription drug product that is fully consistent with the labeling approved by the United States Food and Drug Administration or standard medical practice has led or will lead to affordability challenges for the State health care system or high out-of-pocket costs for patients"[34] (*i.e.*, causes affordability challenges). As part of this overall process, if the Board finds that use of a drug has created an affordability challenge, the Board may develop and recommend policy actions, and may set an upper payment limit.

The Cost Review Study Process is made up of five overall phases: Identify, Select, Collect, Analyze, and Results.

[34] Md. Code Ann., Health-General § 21-2C-09(b)(1).

Identify

The Cost Review Study process starts with the identification of drugs that are eligible for study in accordance with Health-General Article § 21-2C-08(c) and the additional criteria identified by the Board in COMAR 14.01.04.02.D. Staff provides the Board with a dashboard that contains information about the drugs that meet certain statutory and regulatory criteria. The Board may receive an updated dashboard at the beginning of each calendar year.

Select

From the dashboard, the Board selects a subset of drugs eligible for study to send to the Prescription Drug Affordability Stakeholder Council (Stakeholder Council) for comment and input.

In March 2024, the Board referred eight drugs to the Stakeholder Council for input (Biktarvy, Dupixent, Farxiga, Jardiance, Ozempic, Skyrizi, Trulicity, and Vyvanse).

In May 2024, after considering public and Stakeholder Council input, the Board selected six drugs for study: Dupixent, Farxiga, Jardiance, Ozempic, Skyrizi, and Trulicity. In 2025, the Board moved forward with the selected drugs.

Collect

The Board then collects the data necessary to conduct the Cost Review Study. Through the Request for Information (RFI), which is directed to manufacturers, wholesalers, payors, and pharmacy benefit managers, the Board requests and collects data to inform and support the Board's analysis and preliminary determination.

In July 2024, the Board issued a Request for Information for four drugs: Farxiga, Jardiance, Ozempic, and Trulicity. In June 2025, the Board issued an RFI for two drugs: Dupixent and Skyrizi.

Analyze

For each drug under study, the Board analyzes the elements in the Cost Review Study Process, as set forth in COMAR 14.01.04.06. Staff then develops Dossiers containing information relevant to each drug.

Dossiers for Farxiga, Jardiance, Ozempic, and Trulicity were posted throughout 2025.

Ultimately, the Board determines if the studied drug has led or will lead to an affordability challenge.

Current regulations provide for a non-final "preliminary determination" of whether a drug has or will lead to affordability challenges. If the Board makes a preliminary determination that a drug may lead to affordability challenges, the Board can proceed with its Policy Review Process to identify and implement policies that may help make those drugs more affordable for patients and the state, including setting Upper Payment Limits for state and local government. The Board began to implement the Policy Review Process in 2025.

Prescription Drug Products that were Subject to Board Review:

In March 2024, the Board referred eight drugs eligible for a cost review study (Biktarvy, Dupixent, Farxiga, Jardiance, Ozempic, Skyrizi, Trulicity, and Vyvanse) to the Prescription Drug Affordability Stakeholder Council for input.

After careful review, the Board selected six of those drugs for study in a cost review study during the July 2024 Board meeting:

- Farxiga (dapagliflozin)
- Jardiance (empagliflozin)
- Ozempic (semaglutide)
- Trulicity (dulaglutide)
- Dupixent (dupilumab)
- Skyrizi (risankizumab)

In July 2024, the Board issued the RFI for Farxiga, Jardiance, Ozempic, and Trulicity. In May 2025, the Board issued the RFI for Dupixent and Skyrizi.

The Board posted drafts of dossiers for Farxiga, Jardiance, Ozempic, and Trulicity throughout 2025. The final versions of dossiers for Farxiga and Jardiance were posted on July 18, 2025 (updated on July 23, 2025). The final versions of dossiers for Ozempic and Trulicity were posted on November 4, 2025.

Staff expects to post dossiers for Dupixent and Skyrizi at the beginning of 2026.

Preliminary Determination and Draft Cost Review Study Report:

Based on information received in response to the RFIs and the information contained in the Dossiers, the Board conducted the analyses specified in regulation. *See* COMAR 14.01.04.05.

Farxiga

In July 2025, the Board made a preliminary determination that:

(1) the use of Farxiga has created an affordability challenge for the State health care system;
(2) the use creating the affordability challenge was consistent with the labeling approved by the FDA or standard medical practice; and
(3) the circumstances under which use of the drug has or will lead to an affordability challenge are:
    (a) the percentage change in wholesale acquisition cost (WAC) over time is substantially larger than the percentage change in inflation (rate of increase in inflation);
    (b) at the 90th percentile, patient out of pocket (OOP) cost in certain markets is disproportionate to the net cost paid by payors; and
    (c) total gross spending for Farxiga for state and local governments exceeds 1% of gross prescription drug spend for state and local governments.

The Board adopted Board Resolution 2025-01, reflecting this preliminary determination for Farxiga.

Jardiance

In July 2025, the Board made a preliminary determination that:

(1) the use of Jardiance has created an affordability challenge for the State health care system;
(2) the use creating the affordability challenge was consistent with the labeling approved by the FDA or standard medical practice; and
(3) the circumstances under which use of the drug has or will lead to an affordability challenge are:
    (a) the percentage change in wholesale acquisition cost (WAC) over time is substantially larger than the percentage change in inflation (rate of increase in inflation);
    (b) at the 90th percentile, patient out of pocket (OOP) cost in certain markets is disproportionate to the net cost paid by payors; and
    (c) total gross spending for Jardiance for state and local governments exceeds 1.8% of gross prescription drug spend for state and local governments.

The Board adopted Board Resolution 2025-02, reflecting this preliminary determination for Jardiance.

After the Board made preliminary determinations that Farxiga and Jardiance have each created an affordability challenge, it began the Policy Review Process.

Ozempic

In November 2025, the Board made a preliminary determination that:

(1) the use of Ozempic has created an affordability challenge for the State health care system;
(2) the use creating the affordability challenge was consistent with the labeling approved by the FDA or standard medical practice; and
(3) the circumstance under which use of the drug has or will lead to an affordability challenge is:
    (a) total gross spending for Ozempic for state and local governments exceeds 4.87% of gross prescription drug spend for state and local governments (public session).

The Board adopted Board Resolution 2025-03, reflecting this preliminary determination for Ozempic.

Trulicity

In November 2025, the Board made a preliminary determination that:

(1) the use of Trulicity has created an affordability challenge for the State health care system;
(2) the use creating the affordability challenge was consistent with the labeling approved by the FDA or standard medical practice; and
(3) the circumstances under which use of the drug has or will lead to an affordability challenge are:
    (a) the percentage change in WAC over certain periods is substantially larger than the percentage change in inflation (rate of increase in inflation) (closed session)
    (b) total gross spending for Trulicity for state and local governments exceeds 2.27% of gross prescription drug spend for state and local governments (public session).

The Board adopted resolution 2025-04, reflecting this preliminary determination for Trulicity.

The Board is continuing to conduct the Cost Review Study Process for Dupixent and Skyrizi, and expects to make a preliminary determination on whether those drugs have led or will lead to affordability challenges in early 2026.

Policy Review Process and Upper Payment Limits

After making preliminary determinations that Farxiga and Jardiance have created affordability challenges to the State healthcare system (July 2025), the Board engaged the public and community through the Policy Review Process.

The Board engaged in a multifaceted Information Gathering process. *See* COMAR 14.01.05.04. This included: two public Informational Hearings in early September 2025 to obtain input from the public about the drivers of the affordability challenge and possible policy actions to redress those drivers; Stakeholder Council Input; and Board staff research and analysis.

In September 2025, staff presented the proposed drivers of the affordability challenges identified by the Board, and proposed policy solutions. The Board recommended moving forward with investigating the following non-UPL policy recommendations:

- Wholesale Acquisition Cost (WAC) Inflation Penalty: Manufacturers would pay a penalty on the gross Maryland revenue attributable to the increase in WAC above inflation for the drug.
- Navigator Program: Maryland can establish a patient assistance program, similar to the Kentucky Prescription Assistance Program, that organizes a network of navigator experts that use a technology vendor to quickly search for, identify, and coordinate existing assistance programs offered by prescription drug companies to help patients reduce their out-of-pocket prescription drug costs.
- Delinking PBM Compensation from Rebates: PBM compensation would be based on a negotiated flat rate rather than rebates.

The Board also recommended moving forward with the process for establishing an Upper Payment Limit for state and local government for Farxiga and Jardiance. The next step in this process was for the staff to recommend, and the Board to approve, a framework for setting a UPL.

Staff presented on the Farxiga Upper Payment Limit Framework and Jardiance Upper Payment Limit Framework at the public Board meeting in November 2025. The Board approved for staff to move forward drafting a methodology for the Upper Payment Limit frameworks for Farxiga and Jardiance as discussed in the open session.

The next step is for Board staff to publish the methodology documents for the Upper Payment Limits. The Board looks forward to publishing these documents and receiving public comment to inform its future work regarding Upper Payment Limits.

Legislation Concerning the Maryland PDAB

In 2025, Maryland SB0357/HB0424 Prescription Drug Affordability Board - Authority and Stakeholder Council Membership (Lowering Prescription Drug Costs for All Marylanders Now Act) went into effect.

This legislation expanded existing Board authority to implement Upper Payment Limits on certain drugs purchased by state and local governments to include all purchases and payer reimbursements in the state. Notably, this authority is contingent on the PDAB setting Upper Payment Limits on two prescription drugs in accordance with § 21–2C–14 of 24 the Health – General Article and each Upper Payment Limit being in effect for 1 year.

Among other things, this legislation also added provisions relating to drug shortages, updated the Stakeholder Council composition to include three additional members (one representative of the rare disease community, one representative of oncologists, and one representative of a patient advocacy organization), and updated reporting requirements for the Board if it sets a new Upper Payment Limit.

KEY THEMES AND ISSUES AFFECTING PRESCRIPTION DRUG AFFORDABILITY

In 2025, staff continued to track the following key themes affecting prescription drug prices: federal updates, including the Inflation Reduction Act, 340B Drug Pricing Program, tariffs, rise of direct-to-consumer sales, and transparency; glucagon-like peptide-1 receptor agonists (GLP-1 RAs); biosimilar medications; Pharmacy Benefit Manager (PBM) reform; Maryland's biotechnology landscape; and Prescription Drug Affordability Boards.

Federal Updates:

Inflation Reduction Act

The 2022 Inflation Reduction Act (IRA) limits how much drugmakers can raise prices for treatments offered under Medicare, the federal health plan for people aged 65 or more and people under 65 who are disabled, have end-stage renal disease (ESRD), or have amyotrophic lateral sclerosis (ALS). The IRA allows the Medicare program to negotiate with drug companies for the price of a limited number of existing drugs. It also limits out-of-pocket spending for Medicare beneficiaries to $2,000 per year and out-of-pocket costs for insulin to $35 per month. This legislation does not limit what can be charged for new medicines.

In 2023, 10 drugs were selected for the first cycle of Medicare price negotiations. In August 2024, the Centers for Medicare and Medicaid Services (CMS) announced the negotiated drug prices for the initial round of 10 drugs, revealing significant discounts ranging from 38-79% when compared to 2023 list prices.[35] These prices, listed below, will go into effect on January 1, 2026.[36]

[35] ASPE (Assistant Secretary for Planning and Evaluation). *Medicare Drug Price Negotiation Program: Medicare Prices Negotiated for 2026 Compared to List and U.S. Market Prices (IRA Research Series Issue Brief)*. U.S. Department of Health and Human Services. 15 Aug. 2024. Available at: https://aspe.hhs.gov/sites/default/files/documents/3e8abec86039ac0ed674a8c5fac492e3/price-change-over-time-brief.pdf (Last accessed 24 Nov. 2025).
[36] https://www.cms.gov/newsroom/fact-sheets/medicare-drug-price-negotiation-program-negotiated-prices-initial-price-applicability-year-2026

Table 1. Negotiated Prices for Medicare Part D Drugs Subject to First Negotiation Cycle

Drug Name	Price Per 30-Day Supply	Discount From 2023 List Price
Januvia	$113	79%
Fiasp; Fiasp FlexTouch; Fiasp PenFill; NovoLog; NovoLog FlexPen; NovoLog PenFill	$119	76%
Farxiga	$178.50	68%
Enbrel	$2,355	67%
Jardiance	$197	66%
Stelara	$4,695	66%
Xarelto	$197	62%
Eliquis	$231	56%
Entresto	$295	53%
Imbruvica	$9,319	38%

In January 2025, CMS announced the list of 15 drugs for the second cycle of price negotiations. The deadline for participating drug companies to accept or reject a final Maximum Fair Price offer from CMS was October 31, 2025. The negotiation period officially ended on November 1, 2025. In November 2025, CMS released the following negotiated prices, with discounts off of 2024 list prices ranging from 38% to 85%.[37] These MFPs will go into effect on January 1, 2027.

[37] https://www.cms.gov/files/document/fact-sheet-negotiated-prices-ipay-2027.pdf

Table 2. Negotiated Prices for Medicare Part D Drugs Subject to Second Negotiation Cycle

Drug Name	Price Per 30-Day Supply	Discount From 2024 List Price
Ozempic; Rybelsus; Wegovy	$274	71%
Trelegy Ellipta	$175	73%
Xtandi	$7,004	48%
Pomalyst	$8,650	60%
Ofev	$6,350	50%
Ibrance	$7,871	50%
Linzess	$136	75%
Calquence	$8,600	40%
Austedo; Austedo XR	$4,093	38%
Breo Ellipta	$67	83%
Xifaxan	$1,000	63%
Vraylar	$770	44%
Tradjenta	$78	84%
Janumet; Janumet XR	$80	85%
Otezla; Otezla XR	$1,650	65%

Staff will continue to closely monitor CMS updates regarding Inflation Reduction Act implementation. Additionally, staff will continue to monitor the impact of Medicare price negotiations on government savings, beneficiary out-of-pocket costs, pharmaceutical research and development, Medicare Part D payer formulary control, and generic and biosimilar competition.

340B Drug Pricing Program

The 340B Drug Pricing Program is a federal program that enables covered entities to "stretch scarce federal resources" by obtaining outpatient drugs from manufacturers participating in Medicaid at significantly reduced prices.[38] The program has functioned using upfront discounts provided by the manufacturers to the covered entities.

Recent litigation has focused on various aspects of the 340B Program, including federal enforcement regarding contract pharmacy use, state (including Maryland) regulation of contract pharmacy use, use of a rebate model, and scope of the "patient" definition.[39] Staff is continuing to monitor the litigation landscape surrounding the 340B Program.

In July 2025, the Health Resources and Services Administration (HRSA) announced a new, voluntary 340B Rebate Model Pilot Program for drugs on the Centers for Medicare and Medicaid Services (CMS) Medicare Drug Price Negotiation Selected Drug List for year 2026. This program applies to qualifying manufacturers that meet specific criteria and are approved to participate. The official start date is January 1, 2026.

Under this pilot program, covered entities will receive back-end rebates on select drugs from participating manufacturers instead of continuing to receive the discounts upfront. HRSA is implementing this pilot program to "ensure a fair and transparent 340B rebate model process" after stakeholders have addressed concerns regarding accountability, transparency, and adherence to the 340B statute.[40]

In accordance with 2024 House Bill 1056/Senate Bill 0986, the Board shall conduct a study on:[41]

> (i) the current implementation and scope of the 340B Program in the State;
> (ii) the implementation and impact of the implementation of Section 1 of [the] Act; and
> (iii) the finances of the Program in the State, including how covered entities reinvest savings realized from the Program.

On or before July 1, 2026, the Board shall report its findings and recommendations from the study to the Senate Finance Committee and the House Health and Government Operations Committee.

[38] https://www.hrsa.gov/opa
[39] https://www.everycrsreport.com/files/2025-09-10_R48696_968e63d4db509b344683440b5dbbda2e7171bf67.pdf
[40] https://www.hrsa.gov/about/news/press-releases/rebate-model-pilot-program
[41] https://mgaleg.maryland.gov/mgawebsite/Legislation/Details/HB1056?ys=2024RS&search=True

Tariffs

In September 2025, new 100% tariffs were announced for branded or patented pharmaceutical products from companies not breaking ground or undergoing construction on a pharmaceutical manufacturing plant in America. The announcement stated that these tariffs would be imposed as of October 1, 2025, but the White House announced a pause on the tariffs while it is still negotiating agreements with pharmaceutical companies.

Some pharmaceutical companies have made commitments to increase U.S. manufacturing, cut prices, and participate in direct-to-consumer sales, thereby receiving multi-year exemptions from these tariffs.

Staff will continue to monitor any impacts that pharmaceutical tariffs may have on the pharmaceutical market, supply chain, consumer drug prices, access to care, and innovation.

Direct-To-Consumer Sales

In 2025, several pharmaceutical companies have announced new plans to enable direct-to-consumer (DTC) sales for certain medications, usually at reduced prices.[42] Platforms include the manufacturer's own website, the manufacturer's own pharmacy, and future websites, including the government-run TrumpRx.gov which will launch in early 2026 to offer prescription drugs for reduced prices.

Staff will continue to monitor impacts of DTC platforms on price transparency, savings, patient access, and any potential unintended consequences.

Transparency: Real-Time Benefit Tool

Effective October 1st, 2025, the U.S. Department of Health and Human Services (HHS) issued a final rule concerning a real-time prescription drug benefit tool to "compare drug prices, view out-of-pocket costs, and access prior authorization requirements."[43] Using this tool, health care providers that use certified health IT systems will be able to "submit prior authorizations electronically, select drugs consistent with a patient's insurance coverage, and exchange electronic prescription information with pharmacies and insurance plans."[44]

This final rule is part of a larger effort by HHS to improve drug cost transparency and reduce the burden on patients and clinicians. Staff is continuing to track updates regarding this tool.

[42] https://www.reuters.com/business/healthcare-pharmaceuticals/big-pharma-firms-announce-direct-to-consumer-sales-price-cuts-us-2025-10-13/
[43] https://www.hhs.gov/press-room/hhs-prescription-drug-price-transparency-rule.html
[44] *Id.*

Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RAs):

The use of GLP-1 RAs for diabetes and weight loss has continued to grow, and the therapeutic potential of FDA-approved GLP-1 RAs is expected to continue rising as manufacturers continue to seek clinical data and approval for expanding indications.

In February 2025, the FDA declared the semaglutide (Ozempic, Wegovy) and tirzepatide (Mounjaro, Zepbound) shortages resolved. In June 2025, the FDA declared the dulaglutide (Trulicity) shortages resolved.

A study published in April 2025 analyzed annual total U.S. spending on GLP-1 RAs from 2018 to 2023 among adults aged 18 or older.[45] The data analyzed captured 85% of retail and 74% of mail order fills for GLP-1 RA prescriptions.[46] When adjusted for inflation using 2023 dollars, total spending by patients and insurers on GLP-1 RAs at the point of sale increased by more than 500% between 2018 ($13.7 billion) and 2023 ($71.7 billion).[47]

While many patients continue to face barriers to GLP-1 RA access, various direct-to-consumer platforms have presented new channels for patient access (see *Direct-to-Consumer Sales*, above). Staff is continuing to track updates regarding these developments.

Biosimilar Medications

In 2024, savings from FDA-approved biosimilar medicines increased to $20.2 billion.[48] Since the first biosimilar entry to market in 2015, biosimilar medicines have saved a total of $56.2 billion and provided 3.3 billion total days of patient therapy.[49] Without biosimilar competition, 460 million incremental days of patient therapy would not have occurred.[50]

As the U.S. biosimilars market continues to grow, barriers to market entry and uptake remain prevalent, limiting the impact biosimilars can have on more affordable patient care. In August 2025, HHS published a final report on "U.S. Biosimilar Market Entry Challenges and Facilitating Factors."[51] As part of this final report, researchers assessed the costs of several barriers to entry and estimated the value of incentives for reducing such barriers.

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[45] https://pmc.ncbi.nlm.nih.gov/articles/PMC11966331/#:~:text=The%20study%20found%20that%20spending%20changed%20by,(Mounjaro)**%2017%25%20of%20total%20spending%20in%202023

[46] *Id.*

[47] *Id.*

[48] https://accessiblemeds.org/wp-content/uploads/2025/09/AAM-2025-Generic-Biosimilar-Medicines-Savings-Report-WEB.pdf

[49] *Id.*

[50] https://accessiblemeds.org/wp-content/uploads/2025/09/AAM-2025-Generic-Biosimilar-Medicines-Savings_Key-Advocacy-Takeways_Fact-Sheet.pdf

[51] https://aspe.hhs.gov/sites/default/files/documents/2d5c0a194c180b52d1c760d3bb09f70a/Biosimilars%20Final%20Report_250825_v508.pdf

In 2025, the FDA published several guidance documents regarding biosimilars. In September 2025, the FDA published a Guidance for Industry entitled "Development of Therapeutic Protein Biosimilars: Comparative Analytical Assessment and Other Quality-Related Considerations."[52] In October 2025, the FDA published a Draft Guidance for Industry on "Scientific Considerations in Demonstrating Biosimilarity to a Reference Product: Updated Recommendations for Assessing the Need for Comparative Efficacy Studies."[53] In this draft guidance, the FDA recommends streamlined approaches to demonstrating biosimilarity and states that comparative efficacy studies may not be necessary to demonstrate biosimilarity. These updates reflect an ongoing effort to ease outdated regulatory burdens for biosimilar approval, decrease costs for biosimilars to gain market entry, and increase patient access to biosimilars.

Staff will continue to monitor federal and state biosimilar developments and related savings.

Pharmacy Benefit Manager (PBM) Reform

Federal and state efforts to reform pharmacy benefit management continued throughout 2025.

PBM reform has proven difficult to enact. While the federal One Big Beautiful Bill Act initially contained PBM reform provisions when proposed, those provisions were not included in the final enacted version. In July 2025, the bipartisan PBM Reform Act of 2025 was introduced in the U.S. House of Representatives.[54] Among other provisions, this legislation would ban Medicaid "spread pricing," increase transparency in pharmacy reimbursement for Medicaid transactions, delink PBM compensation from the cost of medications under Medicare Part D, increase prescription drug plan transparency, and require certain enforcement from CMS.

Recent state legislative action to regulate PBMs has been diverse yet prevalent across all 50 states, with key themes including transparency, rebate pass-through mandates, PBM ownership of pharmacies, PBM licensing, and de-linking provisions.[55]

Ongoing federal and state litigation involving PBMs likewise spans many topics and assertions, including but not limited to anti-competitive practices, perverse drug rebates, deceptive marketing, PBM ownership of pharmacies, price-fixing, and breach of fiduciary duty under ERISA. Staff will continue to monitor nationwide PBM litigation.

PBM reform continues to be an issue for Maryland. Maryland House Bill 813/Senate Bill 438, enacted during the 2025 legislative session, directed the establishment of a workgroup to study PBMs and pharmacist reimbursement. In consultation with the PDAB, the Maryland Insurance

[52] https://www.fda.gov/media/159261/download
[53] https://www.fda.gov/media/189366/download
[54] https://www.congress.gov/bill/119th-congress/house-bill/4317
[55] https://nashp.org/state-tracker/state-drug-pricing-laws-2017-2025/

Administration and Maryland Department of Health released this workgroup's interim report draft to the public in October 2025.[56]

As part of its policy review work, PDAB staff identified possible drivers of affordability challenges based on incentives in the PBM market and recommended de-linking reimbursement from rebates. The Board and staff are continuing to analyze policy options in the PBM space as the PDAB continues to work with other state agencies through the PBM workgroup.

Maryland's Biotechnology Landscape

Maryland continues to explore policies and opportunities to promote a robust biotechnology sector in the state. In June 2025, the Prescription Drug Affordability Stakeholder Council (Stakeholder Council) invited the Maryland Tech Council to present[57] on opportunities and policies to support a robust and innovative biotechnology sector in Maryland.

In Fall 2025, AstraZeneca announced a $2 billion investment in Maryland as the company plans to expand its biologics manufacturing facility in Frederick and construct a new innovative molecule facility in Gaithersburg.[58] This follows announcements from AstraZeneca to open a new cell therapy manufacturing facility in Rockville.[59]

Prescription Drug Affordability Boards

Prescription Drug Affordability Boards continue to operate across the United States, with varying levels of authority, funding, and priorities. As of July 2025, nine states had active Prescription Drug Affordability Boards. New Hampshire's PDAB was dissolved as of July 1, 2025, due to 2026 biennium state budget constraints.[60]

Only PDABs in Maryland, Colorado, Minnesota, and Washington have authority to both conduct affordability reviews and set UPLs for certain medications. Colorado's PDAB has been undergoing litigation surrounding its UPL rulemaking process.

[56] https://insurance.maryland.gov/Consumer/Documents/agencyhearings/PBM-Workgroup-Interim-Report-Public-Exposure-Draft-10.30.25.pdf
[57] https://pdab.maryland.gov/Documents/presentations/2025/MTC%20PDAB%20PPT%20%281%29.pdf
[58] https://www.astrazeneca.com/media-centre/press-releases/2025/astrazeneca-plans-dollar2-billion-manufacturing-investment-in-maryland-supporting-2600-jobs-and-catalysing-economic-growth.html
[59] *Id.*
[60] https://www.dhhs.nh.gov/sites/g/files/ehbemt476/files/inline-documents/sonh/letter-dissolving-pdab.pdf

CONCLUSION: BOARD RECOMMENDATIONS ON FURTHER LEGISLATION TO MAKE PRESCRIPTION DRUG PRODUCTS MORE AFFORDABLE IN THE STATE

In 2025, the Board made significant progress implementing the Cost Review Study Process and the Policy Review Process which considers Upper Payment Limits. The Board will continue this work in 2026.

The Board may support legislation related to the following key initiatives discussed by Board in meetings over the course of the year:

1. Transparency related to the cost of prescription drugs: Throughout the year, the Board and staff have discussed the limitations of the pricing data that is available to policy makers, especially related to the cost of prescription drugs, net of rebates and discounts. This limitation has created challenges for the Board to successfully complete and implement their work. The Board may support legislation that promotes reporting of this data to the State.
2. Patient navigation services: During the Policy Review Process for Farxiga and Jardiance, the Board and staff identified and supported the establishment of navigator services to help Maryland patients access existing resources, such as patient assistance programs. The Board may support legislation that establishes this program and provides these services for Maryland patients.
3. Biosimilar interchangeability and competition: In recent annual reports and throughout the year, the Board and staff have noted that the biosimilar market is not providing the market competition seen in the generics market. The Board may support legislation that would promote a more competitive biosimilar market in the state.

Appendix A. Board Timelines and Work on Cost Review Study Process and Upper Payment Limits

Please see Board website for more information, including but not limited to agendas, minutes, meeting recordings, presentations, and documents.

2025 Board Meetings with Summaries of Select Items:

- January 27, 2025
    - Opportunity for written public comment concerning Farxiga and Jardiance in connection with cost review study, the Board's pending decisions, or the Board's general work
    - Opportunity for oral public comment concerning Farxiga and Jardiance in connection with cost review study or another agenda item
    - Board approved amendments to COMAR 14.01.04.05 Cost Review Study
- February 26, 2025 (Ad-Hoc)
    - Opportunity for written public comment concerning the Board's pending decisions or general work
    - Opportunity for oral public comment concerning an agenda item
    - Work session concerning proposed amendments to COMAR 14.01.01.01, new COMAR 14.01.01.06, and new COMAR 14.01.05
- March 24, 2025
    - Opportunity for written public comment concerning the Board's pending decisions or general work
    - Opportunity for oral public comment concerning an agenda item
    - Staff presentation on select sections of Farxiga Cost Review Study Dossier
    - Review of comments received on proposed amendments to COMAR 14.01.01.01, new COMAR 14.01.01.06, and new COMAR 14.01.05
    - Board approved proposed amendments to COMAR 14.01.01.01, new COMAR 14.01.01.06, and new COMAR 14.01.05
- May 19, 2025
    - Opportunity for written public comment concerning the Board's pending decisions or general work
    - Opportunity for oral public comment concerning an agenda item
    - Staff presentation on initial version of Farxiga Dossier, including organization and attached exhibits
- June 23, 2025 (Special)
    - Opportunity for written public comment concerning the Board's pending decisions or general work
    - Opportunity for oral public comment concerning an agenda item
    - Board approved Board Management Software Contract

- July 28, 2025
    - Opportunity for written public comment concerning the Board's pending decisions or general work
    - Opportunity for oral public comment concerning an agenda item
    - Staff overview of cost review study process and policy review process
    - Staff presentation on Farxiga Cost Review Study Dossier
    - Board approved motion to make a preliminary determination that the use of Farxiga has created an affordability challenge for the State health care system and that the use creating the affordability challenge was consistent with the labeling approved by the FDA or standard medical practice
        - Board identified the following three circumstances:
            - (1) The percentage change in wholesale acquisition cost (WAC) over time is substantially larger than the percentage change in inflation (rate of increase in inflation)
            - (2) At the 90th percentile, patient out of pocket (OOP) cost in certain markets is disproportionate to the net cost paid by payors
            - (3) Total gross spending for Farxiga for state and local governments exceeds 1% of gross prescription drug spend for state and local governments
        - Preliminary determination and identified circumstances regarding Farxiga are reflected in Board Resolution 2025-01
    - Staff presentation on Jardiance Cost Review Study Dossier
    - Board approved motion to make a preliminary determination that the use of Jardiance has created an affordability challenge for the State health care system and that the use creating the affordability challenge was consistent with the labeling approved by the FDA or standard medical practice
        - Board identified the following three circumstances:
            - (1) The percentage change in wholesale acquisition cost (WAC) over time is substantially larger than the percentage change in inflation (rate of increase in inflation)
            - (2) At the 90th percentile, patient out of pocket (OOP) cost in certain markets is disproportionate to the net cost paid by payors
            - (3) Total gross spending for Jardiance for state and local governments exceeds 1.8% of gross prescription drug spend for state and local governments
        - Preliminary determination and identified circumstances regarding Farxiga are reflected in Board Resolution 2025-02
- September 29, 2025 (Rescheduled from September 15, 2025)
    - Opportunity for written public comment concerning the Board's pending decisions or general work

    - Opportunity for oral public comment concerning an agenda item
    - Staff presentation: Cost Review Study Process Preliminary Policy Recommendations
- November 17, 2025
    - Opportunity for written public comment concerning the Board's pending decisions or general work
    - Opportunity for oral public comment concerning an agenda item
    - Oral staff presentation: Overview - Cost Review Study Process
    - Staff presentation on Ozempic Cost Review Study
    - Board approved motion to make a preliminary determination that the use of Ozempic has created an affordability challenge for the State health care system and that the use creating the affordability challenge was consistent with the labeling approved by the FDA or standard medical practice
        - Board identified the following as a circumstance:
            - Total gross spending for Ozempic for state and local governments exceeds 4.87% of gross prescription drug spend for state and local governments (public session)
        - Preliminary determination and identified circumstance regarding Ozempic are reflected in Board Resolution 2025-03
    - Staff presentation on Trulicity Cost Review Study
    - Board approved motion to make a preliminary determination that the use of Trulicity has created an affordability challenge for the State health care system and that the use creating the affordability challenge was consistent with the labeling approved by the FDA or standard medical practice
        - Board identified the following two circumstances:
            - (1) The percentage change in WAC over certain periods is substantially larger than the percentage change in inflation (rate of increase in inflation) (closed session)
            - (2) Total gross spending for Trulicity for state and local governments exceeds 2.27% of gross prescription drug spend for state and local governments (public session)
        - Preliminary determination and identified circumstances regarding Trulicity are reflected in Board Resolution 2025-04
    - Staff presentation on Farxiga: Upper Payment Limit Framework
    - Staff presentation on Jardiance: Upper Payment Limit Framework
    - Board approved motions for staff to move forward drafting recommendations on Upper Payment Limit frameworks for Farxiga and Jardiance
- December 8, 2025 (Special)
    - Upcoming

2025 Stakeholder Council Meetings with Summaries of Select Items:

- April 28, 2025
    - Opportunity for public comment, written and oral, on agenda items
    - Learning Series Presentation and Discussion: Drug Pricing and Supply Chain Overview
- June 23, 2025
    - Opportunity for public comment, written and oral, on agenda items
    - Learning Series Presentation and Discussion: Federal Government Drug Pricing Update
    - Learning Series Presentation and Discussion: Biotech and Life Sciences Update in Maryland
- August 25, 2025
    - Opportunity for public comment, written and oral, on agenda items
    - Staff presentation: Cost Review Study Process Update and Next Steps
    - Staff presentation: Board Solicited Stakeholder Council Input
- December 15, 2025
    - Upcoming