

Maryland PDAB Annual Report

Md. Code Ann., Health-General § 21-2C-09(c)

PDAB Meeting

December 8, 2025

PDAB Staff



Health-General § 12-2C-09(c) - Report Requirement

On or before December 31, 2020, and each December 31 thereafter, the Board shall submit to the Senate Finance Committee and the House Health and Government Operations Committee, in accordance with § 2-1257 of the State Government Article, a report that includes:

- (1) Price trends for prescription drug products;
- (2) The number of prescription drug products that were subject to Board review and the results of the review; and
- (3) Any recommendations the Board may have on further legislation needed to make prescription drug products more affordable in the State.

Md. Code Ann., Health-General § 21-2C-09(c)

Note: This presentation is not all-inclusive and is not intended to be a complete summary of the published report.



Price Trends

- 2024 U.S. pharmaceutical expenditures grew 10.2% compared to 2023, totaling \$805.9 billion
- Top drugs for overall expenditures: semaglutide (e.g., Ozempic, Wegovy), tirzepatide (Zepbound, Mounjaro), adalimumab (e.g., Humira and biosimilars), apixaban (Eliquis), and empagliflozin (Jardiance)
- Pharmaceutical prices had an overall slight decrease of 0.2%
- Net price growth was overall flat
- Significant barriers to medication access persist, as patients do not fill over half of new prescriptions for novel medicines due to benefit design and high costs



2025 Maryland PDAB Actions - Regulatory Update

- Updated Cost Review Study Process to account for Policy Review Process outlined in Upper Payment Limit Action Plan, which was approved by Legislative Policy Committee in October 2024. See COMAR 14.01.04.05.
- Approved amendments to COMAR 14.01.01.01, new regulation COMAR 14.01.01.06, and a new chapter of regulations COMAR 14.01.05 Policy Review, Final Action, Upper Payment Limits



2025 Maryland PDAB Actions - Selected Drugs

- Farxiga (dapagliflozin) - Board made preliminary determination
- Jardiance (empagliflozin) - Board made preliminary determination
- Ozempic (semaglutide) - Board made preliminary determination
- Trulicity (dulaglutide) - Board made preliminary determination
- Dupixent (dupilumab) - Staff currently working on dossier; expected early 2026
- Skyrizi (risankizumab) - Staff currently working on dossier; expected early 2026



2025 Maryland PDAB Actions - 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.



2025 Maryland PDAB Actions - 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.



2025 Maryland PDAB Actions - 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).



2025 Maryland PDAB Actions - 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).



2025 Maryland PDAB Actions - Policy Review Process and Upper Payment Limits - Part I

- Board engaged public and community through Policy Review Process
 - Board held two public Informational Hearings in September 2025 to obtain input from the public about the drivers of the affordability challenges for Farxiga and Jardiance and possible policy actions
 - Stakeholder Council input
 - Board staff research and analysis



2025 Maryland PDAB Actions - Policy Review Process and Upper Payment Limits - Part II

- Board recommended moving forward with investigating the following non-UPL policy recommendations:
 - Wholesale Acquisition Cost inflation penalty
 - Navigator program
 - Delinking PBM compensation from rebates
- Board recommended moving forward with process for establishing an Upper Payment Limit for state and local government for Farxiga and Jardiance
- Staff presented on the Farxiga Upper Payment Limit Framework and Jardiance Upper Payment Limit Framework in November 2025
- Board staff will publish methodology documents for the Upper Payment Limits



Legislation Concerning 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
- Among other provisions, 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
 - 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



Key Themes Affecting Prescription Drug Affordability

- Inflation Reduction Act: Negotiated prices for 10 Medicare Part D drugs subject to first negotiation cycle will go into effect on January 1, 2027; negotiated prices for 15 drugs subject to second cycle were just released
- 340B Drug Program: New 340B Rebate Model Pilot Program; litigation continues
- Tariffs and exemptions for pharmaceutical manufacturing construction
- Direct-to-consumer sales for certain medications, often at reduced prices
- Efforts to increase transparency, including federal real-time benefit tool



Key Themes Affecting Prescription Drug Affordability

- Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RAs): Increased utilization and spending; expanding indications; continued access barriers, direct-to-consumer platforms are presenting new channels for patients
- Biosimilar medications: Market continues to grow, yet barriers to entry persist; recent FDA guidance recommends streamlined approaches to demonstrating biosimilarity
- Pharmacy Benefit Manager (PBM) reform: PBM reform has proven difficult to enact; PBM Reform Act of 2025 has been introduced in the U.S. House of Representatives; ongoing state legislative action, federal and state litigation



Conclusion and Recommendations

- Board may support legislation related to the following initiatives:
 - Prescription drug cost transparency
 - Patient navigation services
 - Biosimilar interchangeability and competition
- Please see the full Annual Report posted on the Board's website for a more complete description of price trends, 2025 Board actions, and key themes affecting prescription drug affordability





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Prescription Drug Affordability Board

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