Policy Review Process and Non-UPL Policies

PDAB Meeting

May 18, 2026

PDAB Staff

MARYLAND
Prescription Drug Affordability Board

Policy Review Process Chronology

- Preliminary Determination - Affordability Challenge 11/17/2025
- Policy Review Process and Preliminary Policy Recommendations 02/23/2026
  - Public Information Hearings 12/16/25 at 1:00 & 6:00 pm
  - Stakeholder Council Input- 12/15/25 PDASC meeting
  - Staff research & analyses; Eligible gov’t entity info

Non-UPL Policies
Ozempic

- **The Board may adopt a final policy recommendation only after the Board has:**
  - Made a final affordability challenge determination; and
  - Adopted the final cost review study report under COMAR 14.01.04.05G.
- **Draft Non-UPL Policy Recommendations**
  - **Patient Navigator Program**
  - GLP-1 Study and Recommendations
  - Plan Design and PBM Reform Study
  - Bulk Purchasing / Subscription Model
  - State Participation in CMMI Models

Patient Navigator Program

Policy Explanation

- The state can implement a patient navigator program modeled after the Kentucky Prescription Assistance Program (KPAP), which is a free service that helps people obtain their prescription medications by identifying and helping them apply to existing medication assistance programs offered by drug companies, discount drug programs, and discount pharmacy programs.

Patient Navigator Program- Implementation Process and Timeline

Phase 1: Strategic Assessment (4 Months): PDAB and state partners conduct an assessment of current state capacity and opportunities to develop navigator program.

Phase 2: Operational Design (5 Months): Staff develops operational protocols and resource library for providing navigator services. Staff can begin tests and soft rollout on ad hoc bases.

Phase 3: Legislative Phase (4 Months): Introduction of funding and full-time equivalent (FTE) allocation legislation to authorize and create the navigator program.

Phase 4: Program Launch (Milestone): Full program launch; develop partner network, and begin patient navigation services.

Patient Navigator Program- Other State Examples

- **Kentucky (House Bill 406 Kentucky Prescription Drug Patient Assistance Program)[5]:**
  - Establishes and funds a community-based service delivery model to reach all 120 Kentucky counties.
  - A small team of 2 full-time state employees and a part-time contractor support a broad network of partner organizations and local advocates.
  - The state team manages the hotline, licenses the software to partners and provides training and oversight for the community network.
- **Washington (SB 5558 Prescription Drug Assistance Foundation (PDAF) / Prescription Drug Assistance Network (PDAN))[6]:**
  - Created a non-profit foundation that provides support for residents with inadequate coverage and distributes grants to fund local patient assistance initiatives across the state.
  - The foundation's program counterpart is a direct-to-consumer hotline where care coordinators guide patients through existing assistance options to find the most affordable ways to access their medications.

5. Kentucky House Bill 406. 2008 Regular Session.
6. Washington Senate Bill 5558. 59th Legislature (2005).

Non-UPL Policy Recommendations Requiring Board Action

- GLP-1 Study and Recommendations
- Plan Design and PBM Reform Study
- Bulk Purchasing / Subscription Model
- State Participation in CMMI Models

GLP-1 Study and Recommendations

- In collaboration with State and Stakeholder partners, the Board will conduct a class-wide, comprehensive assessment of GLP-1s. This study will move beyond individual drug reviews to evaluate the systemic impact of the GLP-1 class on Marylanders and the health care system.
- **Key Interest Areas:**
  - **Market Stability:** Impact of national shortages and the rise in use of compounded alternatives.
  - Benefit Design: Variations in insurance coverage, plan design, and the use of BMI thresholds or prior authorization.
  - **Utilization Patterns:** Trends in off-label usage for obesity versus FDA-approved indications (diabetes, cardiovascular health).
  - **Policy Alignment:** Interplay of Executive Orders, new federal CMMI models (e.g., BALANCE), and value-based arrangements.
  - **Access & Affordability:** Barriers in underserved communities and the fiscal sustainability of state-funded programs.nders and the health care system.

GLP-1 Study and Recommendations- Implementation Process and Timeline

Phase 1: Authorization (1 Month): Board officially votes to authorize the study and establishes core research questions and a stakeholder engagement framework.

Phase 2: Research Phase (12 Months): Board in conjunction with state partners, conducts a 12-month qualitative and quantitative analysis, including actuarial modeling of Maryland claims data and stakeholder testimony.

Phase 3: Reporting (3 Months): Board finalizes findings in a standalone "State of GLP-1 Affordability" report or as a primary feature of the 2027 Annual Report.

Phase 4: Legislative Action (Milestone): Board presents a suite of actionable policy recommendations to the Maryland General Assembly for the Legislative Session.

GLP-1 Study and Recommendations- Other State Examples

Washington (SB 5950 (2024), Section 212(9)): Mandated its Health Care Authority to study coverage options for GLP-1s within the Uniform Medical Plan (UMP), the state's self-insured plan for public employees. The study focuses on cost-modeling and sustainable coverage strategies (e.g., lifestyle management) to ensure that high-cost obesity treatments do not compromise the state's long-term budget.

ICER (Institute for Clinical and Economic Review): In 2025, ICER released an updated "Obesity Evidence Report" noting that while GLP-1s are clinically cost-effective, they pose a "structural threat" to state budgets because the eligible population is so large (>40% of adults).

Massachusetts Health Policy Commission (HPC): In its 2024 Annual Cost Trends Report and GLP-1 DataPoint Series (Issue 27), the HPC identified an eight-fold increase in GLP-1 spending since 2018, primarily driven by a shift toward weight-loss indications. The investigation evaluated how these utilization patterns impact commercial insurance coverage, market competition, and the long-term sustainability of the state's healthcare spending benchmark.

10. Washington SB 5950 (2024), Section 212(9)
11. ICER Obesity Evidence Report (2025)
12. Massachusetts HPC Annual Cost Trends Report (2024)
13. HPC DataPoint Series (Issue 27)

Plan Design and PBM Reform Study and Recommendations

In collaboration with State and Stakeholder partners, the Board will conduct a comprehensive study on pharmacy benefit manager (PBM) practices and health plan design. This assessment aims to address systemic transparency issues and market inefficiencies to provide actionable policy recommendations.

Key Interest Areas:

- **Reimbursement & Fair Competition:** Evaluating reimbursement methods and the cost disparity between commercial and Maryland Medical Assistance contracts.
- **Market Structure:** Analyzing vertical integration, "anti-steering" practices toward PBM-owned pharmacies, and the impact of specialty drug lists.
- **Transparency & Accountability:** Assessing fiduciary duty requirements, delinked compensation (flat-fee) structures, and the "pass-through" of rebates and point-of-sale (POS) discounts.
- **Utilization Management:** Reviewing the prevalence of prior authorizations and the impact of manufacturer rebates on formulary design and biosimilar uptake.

Plan Design and PBM Reform Study and Recommendations - Implementation Process and Timeline

- **Phase 1: Proposal & Framework (1 Month):** Board prepares the scope of the study and establishes the stakeholder engagement framework.
- **Phase 2: Analysis & Modeling (12 Months):** Board, in conjunction with state partners, conducts a 12-month analysis, utilizing actuarial modeling of Maryland claims data and stakeholder testimony.
- **Phase 3: Reporting & Finalization (3 Months):** Board finalizes findings in a standalone "PBM Reform" report or as a feature of the 2027 Annual Report.
- **Phase 4: Policy Recommendation (Milestone):** Presentation of formal policy recommendations to the Maryland General Assembly for the Legislative Session.

Plan Design and PBM Reform Study and Recommendations - Precedents and External Frameworks

- **Federal Trade Commission (FTC):** The FTC's ongoing inquiry into "Prescription Drug Middlemen" serves as a framework, specifically regarding how vertical integration and opaque pharmacy audits impact drug competition and patient costs.
- **National Association of Insurance Commissioners (NAIC):** The NAIC's PBM Working Group provides a blueprint for state-level oversight, including uniform data collection standards, market conduct monitoring, and harmonized licensing requirements across state lines.
- **American Medical Association (AMA):** The AMA's Committee on Medical Service has established a precedent for (1) evaluating the erosion of "physician-led medication management" due to PBM restrictions, and (2) examining DIR fees to inform state-level advocacy

14. FTC Prescription Drug Middlemen (2025)
15. NAIC PBM Working Group (2026)
16. AMA Committee (2019)

Bulk Purchasing/Subscription Model

- Maryland would implement a modified subscription model (often termed the "Netflix Model") for GLP-1 medications. Under this arrangement, the State pays a negotiated, capped annual fee to a single manufacturer in exchange for an expanded or unlimited supply of semaglutide for Medicaid, State Employee, and/or correctional populations. This model provides the manufacturer with a guaranteed revenue stream while ensuring Maryland has predictable, consistent costs regardless of utilization volume.

Bulk Purchasing/Subscription Model - Implementation Process and Timeline

- **Phase 1: Feasibility Study (4 Months):** PDAB and Maryland Medicaid conduct a joint feasibility study to evaluate manufacturer interest and develop multi-year cost savings estimates based on various utilization caps.
- **Phase 2: CMS Submission (3 Months):** MDH submits a State Plan Amendment (SPA) request or waiver request to the Centers for Medicare and Medicaid Services (CMS) for authority to negotiate subscription-based supplemental rebates.
- **Phase 3: Optional Legislative Support (3 Months):** Parallel Legislative Session: Introduction of a "Value-Based Purchasing Act" to provide statutory support (similar to PA HB1470).
- **Phase 4: RFP Issuance (Milestone):** Upon CMS approval, the State issues a request for proposal (RFP) to drug manufacturers for a sole-source subscription contract.
- **Phase 5: Contract Execution (Milestone):** Contract execution with the selected manufacturer(s).
- **Phase 6: Program Launch (Milestone):** Program launch and distribution of GLP-1s on a subscription basis.

Bulk Purchasing/Subscription Model - Other State Examples

- **Louisiana (Hepatitis C):** Louisiana received CMS approval for an SPA allowing a capped annual fee to a manufacturer (Gilead/Asegua) for an unlimited supply of Hep-C antiviral treatments. This model successfully expanded access to thousands of residents while keeping state expenditures fixed.

17. CMS Press Release Louisiana State Plan Amendment (2019)

State Participation in CMMI models

To address the drivers of the identified circumstances leading to an affordability challenge for Ozempic, it is recommended that Maryland Medicaid pursue participation in two new CMMI models. These models leverage Most-Favored-Nation (MFN) pricing to lower state expenditures on GLP-1s and other Covered Outpatient Drugs (CODs).

State Participation in CMMI Models - BALANCE and GENEROUS

BALANCE (Better Approaches to Lifestyle and Nutrition for Comprehensive hEalth) Model : This model allows Maryland to bulk-purchase GLP-1 medications at MFN pricing for Medicaid and Medicare populations. By combining drug access with lifestyle interventions, the state can mitigate the long-term costs of diabetes and cardiovascular disease.

GENEROUS (GENErating cost Reductions fOr U.S. Medicaid) Model: Manufacturers voluntarily provide supplemental rebates that achieve Guaranteed Net Unit Price (GNUP) reflecting the MFN price for Covered Outpatient Drugs (CODs), while participating states apply standardized and transparent coverage criteria for modeled drugs. The state invoices the manufacturer for the supplemental rebate, receives the payment directly, and returns the federal government's share when CMS reduces the amount of federal funding (FMAP) for future Medicaid expenditures.
The state receives supplemental rebates directly from manufacturers, calculated as follows:

Supplemental Rebate = WAC – (GNUP plus URA)

18. CMMI BALANCE Model (2026)
19. CMMI GENEROUS Model (2026)

References

1. Illinois General Assembly. Illinois Compiled Statutes, Chapter 35: Public Health. Illinois General Assembly website. Accessed April 6, 2026. https://www.ilga.gov/Legislation/ILCS/Articles?ActID=4433&ChapterID=35
2. Minnesota Legislature. SF 2744: Omnibus Commerce appropriations bill, 93rd Legislature (2023-2024). Office of the Revisor of Statutes website. Published May 24, 2023. Accessed April 6, 2026. https://www.revisor.mn.gov/bills/93/2023/0/SF/2744/?body=senate
3. Connecticut General Assembly Office of Legislative Research. OLR Bill Analysis: SSB 11, An Act Concerning Prescription Drug Access and Affordability. Connecticut General Assembly website. Published April 2, 2025. Accessed April 6, 2026. https://www.cga.ct.gov/2025/BA/PDF/2025SB-00011-R000420-BA.PDF
4. Massachusetts Legislature. Bill S.2774: An Act investing in the future of our health, 192nd General Court. The General Court of the Commonwealth of Massachusetts website. Introduced March 17, 2022. Accessed April 6, 2026. https://malegislature.gov/Bills/192/S2774
5. Kentucky General Assembly. HB 406: An act relating to appropriations measures providing funding and establishing conditions for the operations of the government of the Commonwealth of Kentucky. 2008 Regular Session. Legislative Research Commission website. Published 2008. Accessed April 6, 2026. https://apps.legislature.ky.gov/record/08rs/hb406.html
6. Washington State Legislature. SB 5558: An act relating to the prescription drug assistance foundation. 59th Legislature, 2005 Regular Session. Washington State Legislature website. Published 2005. Accessed April 6, 2026. https://lawfilesext.leg.wa.gov/biennium/2005-06/Pdf/Bills/Senate%20Bills/5558.pdf
7. Colorado General Assembly. HB25-1094: Pharmacy benefit manager practices. Colorado General Assembly website. Published 2025. Accessed April 6, 2026. https://leg.colorado.gov/bills/hb25-1094
8. Florida Senate. CS/CS/SB 1550: Prescription drugs. Florida Senate website. Published 2023. Accessed April 6, 2026. https://www.flsenate.gov/Committees/BillSummaries/2023/html/1550
9. 3. California State Legislature. SB 41: Pharmacy benefit managers. California Legislative Information website. Published 2025. Accessed April 6, 2026. https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=202520260SB41
10. Washington State Legislature. *Engrossed Substitute Senate Bill 5950*. Washington State Legislature; 2024. Accessed April 23, 2026. https://fiscal.wa.gov/statebudgets/2024proposals/Documents/co/5950-S.SL.pdf
11. Institute for Clinical and Economic Review. *Medications for Weight Management: Final Evidence Report and Meeting Summary*. Institute for Clinical and Economic Review; 2023. Accessed April 23, 2026. https://icer.org/wp-content/uploads/2022/03/ICER_Obesity_Final_Evidence_Report_and_Meeting_Summary_122223.pdf
12. Massachusetts Health Policy Commission. *2024 Health Care Cost Trends Report*. Massachusetts Health Policy Commission; 2024. Accessed April 23, 2026. https://masshpc.gov/sites/default/files/2024_Cost_Trends_Report.pdf
13. Massachusetts Health Policy Commission. DataPoints Issue 27: Blockbuster GLP-1 weight loss drugs in Massachusetts. Massachusetts Health Policy Commission. Published May 2024. Accessed April 23, 2026. https://masshpc.gov/publications/datapoints-series/issue-27-blockbuster-glp-1-weight-loss-drugs-massachusetts
14. US Department of Justice. Formulary and benefit practices and regulatory abuse impacting drug competition. US Department of Justice. Published February 15, 2024. Accessed April 23, 2026. https://www.justice.gov/atr/event/formulary-and-benefit-practices-and-regulatory-abuse-impacting-drug-competition
15. National Association of Insurance Commissioners. Pharmacy Benefit Management (B) Working Group. National Association of Insurance Commissioners. Accessed April 23, 2026. https://content.naic.org/d/pharmacy-benefit-management-wg
16. American Medical Association Council on Medical Service. *CMS Report 5: Alternative Payment Models for Prescription Drugs*. American Medical Association; 2019. Accessed April 23, 2026. https://www.ama-assn.org/system/files/2019-07/a19-cms-report-5.pdf
17. Centers for Medicare & Medicaid Services. CMS approves Louisiana state plan amendment for supplemental rebate agreements using a modified subscription model for hepatitis C therapies. Centers for Medicare & Medicaid Services. Published June 26, 2019. Accessed April 23, 2026. https://www.cms.gov/newsroom/press-releases/cms-approves-louisiana-state-plan-amendment-supplemental-rebate-agreements-using-modified
18. Centers for Medicare & Medicaid Services. Medicare High-Value Drug Strategy: Cell & Gene Therapy (CGT) Access Model. Centers for Medicare & Medicaid Services. Accessed April 23, 2026. https://www.cms.gov/priorities/innovation/innovation-models/balance
19. Centers for Medicare & Medicaid Services. Medicare High-Value Drug Strategy: Accelerating Clinical Evidence (ACE) Model. Centers for Medicare & Medicaid Services. Accessed April 23, 2026. https://www.cms.gov/priorities/innovation/innovation-models/generous

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