Cost Review Study Process
Preliminary Policy Recommendations

PDAB Meeting

January 26, 2025

MARYLAND
Prescription Drug Affordability Board

Program

- Cost Review Study Process
  - Preliminary Determinations
- Overview of Policy Review
- Information Gathering
- Preliminary Policy Recommendations

COMAR 14.01.04.05A- Cost Review Study

November 17, 2025 Board Meeting. The Board had the opportunity to examine:

(1) Whether use of each drug, Ozempic and Trulicity, has led or will lead to:

(a) Affordability challenges to the State health care system; or

(b) High out-of-pocket costs for patients;

(2) Whether the use that has led to affordability challenges or high out-of-pocket costs is consistent with:

(a) The labeling approved by the FDA; or

(b) Standard medical practice.

(3) Identify the circumstances under which the prescription drug product has or will lead to an affordability challenge to the State health care system or high out-of-pocket costs to patients.

The circumstances under which the prescription drug products have led to affordability challenges include:

At the November 17, 2025 meeting, the Board made a preliminary determination that use of Ozempic has created an affordability challenge for the State health care system.

The circumstance under which the prescription drug product has led to affordability challenge include:

- 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).

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The Board also made a preliminary determination that the use of Trulicity has created an affordability challenge for the State health care system.

The circumstances under which the prescription drug product has led to affordability challenges include:

- 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); and
- the percent change in WAC over certain periods is substantially larger than the percentage change in inflation (rate of increase in inflation) (closed session)

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Next Step after Preliminary Determination - Draft Report

- Board staff shall prepare a draft of the preliminary determination cost review report that summarizes:
  - the information considered by the Board in conducting the cost review study,
  - the Board's deliberations,
  - the circumstances or indicia reflecting the affordability challenge, and
  - the Board's preliminary determination.
- The public **may comment on the draft of the preliminary determination cost review report**.
- A preliminary determination **is non-final and subject to revision and modification**.

Next Step after a Preliminary Determination - Policy Review Process

The purpose of the policy review process is to:

(1) Based on the best available information, **confirm the drivers and market conditions causing the affordability challenge phenomena**; and

(2) **Identify the policies that may address those drivers and redress the affordability challenges**.

Policy Review Process and Upper Payment Limit (UPL) Development Policy Review Process

Green= Upper Payment Limit Policy Review Process
Blue= Non-UPL Policy Review Process
Red= Cost Review Study Process

Policy Review Process

The policy review process includes:

(1) Information gathering;

(2) Preliminary policy recommendations;

(a) non-UPL policies; and
(b) UPL policy and the process for setting upper payment limits; and

(3) Final actions

Policy Review Process - Information Gathering

Information Gathering Tools:

(a) Informational hearings;

(b) Stakeholder Council input;

(c) Expert testimony hearings;

(d) Board staff research and analysis; and

(e) Request for eligible governmental entities' information.

Tools Used for Information Gathering for Trulicity and Ozempic are bolded.

Policy Review Process - Information Gathering
COMAR 14.01.05.04(D)(1)- Informational Hearing

Public Information Hearings.

(a) The Board may, through Board staff, convene a hearing to receive input, information, and opinions from the public and stakeholders to inform the consideration and development of policy options including upper payment limits to redress an affordability challenge.

(b) The public informational hearing shall be conducted in accordance with COMAR 14.01.01.06.

December 16, 2025 Informational Hearing (at 1:00 pm)

- December 16, 2025 at 1:00 PM
  - 4 persons: Mark Hobraczk, Jim Gutman, Derek Flowers, George Huntley
  - Exhibit 1: The Notice of Informational Hearing
  - Exhibit 2: AARP, Written Comments, Jim Gutman
  - Exhibit 3: Diabetes Patient Advocacy Coalition, Written Comments, George Huntley
  - Exhibit 4: Maryland HealthCare for All Coalition
  - Exhibit 5: John Plaster, Patient Written Testimony
  - Exhibit 6 and 7: Partnership to Advance Cardiovascular Health (2 comment letters)
  - Exhibit 8: PhRMA
  - Exhibit 9: Eli Lilly

December 16, 2025 Informational Hearing (at 1:00 pm)

4 Persons registered to provide testimony

1. Mark Hobraczk, Ensuring Access Through Collaborative Health Coalition and the Patient Inclusion Council

a. Unintended consequences of UPLs are not just speculative. A Pioneer Institute study showed that patient out-of-pocket costs increased 32% for the first set of drugs under MFP, even before the prices take effect

b. Adverse impacts go beyond higher costs; patients face real prospect of removal from formulary, or of their drugs not being stocked at pharmacies, or of being switched to inferior products

c. Alternative ideas could do more to reduce costs without restricting patient access; shifting to transparent PBM compensation has been shown to reduce annual net drug spending by 15%.

d. Recommends delinking PBMs and reforming how PBMs are paid to reduce selection of high-cost drugs to maximize rebates.

December 16, 2025 Informational Hearing (at 1:00 pm)

2. James Gutman, AARP of Maryland (also a member of PDAB Stakeholder council representing the public, volunteer counsellor for SHIP health program)

a. Interested in policies to address the drivers - PDAB should move quickly for non-UPL policies as it does for UPL policies.

b. These are excellent drugs, but there is a Catch-22 because their increased use has created an affordability challenge

c. Increased affordability could reduce hospitalizations and associated costs.

d. Medicare negotiated prices will not benefit non-medicare patients without action

e. AARP recommends swift movement on UPL and non-UPL options; non-UPL policies may be useful but will take longer to effectuate, and relief is needed now.

December 16, 2025 Informational Hearing (at 1:00 pm)

3. Derek Flowers, Value of Care Coalition

   a. Cost conversations must consider access and patient lives, not just list prices; chronic disease patients are treated most cost-effectively when they receive timely treatment and their illness is stable and well-controlled.

   b. These important drugs are frontline therapies for diabetes and other diseases, described by physicians as essential; they save lives and ICER analysis shows they are cost-effective

   c. Growing competition and utilization changes are already bringing down prices, but these price reductions are not reflected by PDAB reviews that rely on older data

   d. Increased spending has been driven by increased utilization even though prices are not rising overall

   e. UPLs may not benefit patients but will produce increased coinsurance and prior authorization requirements - Colorado Enbrel UPL has already increased administrative burdens for doctors, and may lead to utilization management, PBM rebate reductions, formulary restrictions, and pharmacy deserts

   f. Recommends rebate pass-through, PBM transparency provisions, and plan design changes - these could be beneficial because they help improve access and keep patients healthy to reduce utilization and cost in the long run

December 16, 2025 Informational Hearing (at 1:00 pm)

4. George Huntley, Diabetes Patient Advocacy Coalition

   a. As other speakers have noted, these are essential therapies for type 2 diabetes patients; the driver of higher spending by the state is increased demand, and increased indications for use of these medications; GLP-1 prices are categorically falling rather than rising

   b. PDAB should focus on reducing health spending, not just drug spending; inadvertently decreasing access for these drugs would lead to higher overall health prices

   c. Patients with obesity may purchase direct-to-consumer, but will not get a PBM rebate - they are essentially Sam's club members who aren't getting the membership price

   d. PBM reform could enable rebate pass-through and reduce formulary restrictions; rebate pass-through might lower costs by 50% and enable chronic disease patients to meet their deductible sooner, and delinking PBMs could lower the cost of drugs by 15%

   e. Recommends pass-through rebates, PBM delinking, and requiring PBMs or any health plan to always include the lower cost option for a drug in their class in their formulary

Informational Hearing (continued at 6:00 pm)

- December 16, 2025 at 6:00 PM
  - No persons registered to provide testimony at the December 16, 2025 informational hearing.
  - The hearing was convened at 6:00 p.m. and concluded shortly thereafter.

Policy Review Process - Information Gathering
COMAR 14.01.05.04(D)(2)- Stakeholder Council Input

Stakeholder Council Input.

(a) The Board may request input from the Stakeholder Council. This input can be a request for general input and ideas on policies or more specific requests for specific information.

(b) Board staff may provide the Board with summaries of input from the Stakeholder Council.

Policy Review Process - Information Gathering
COMAR 14.01.05.04(D)(2)- Stakeholder Council Input

Written Comments Submitted for Stakeholder Council meeting

- Comments Received from one Patient Advocacy Coalition:
  - Call for an equivalent evaluation of both UPL and non-UPL policy solutions
  - Concerns about the impact of a UPL on patient access
  - Policy suggestion to de-link PBM compensation from rebates

Policy Review Process - Information Gathering
COMAR 14.01.05.04(D)(2)- Stakeholder Council Input

Summary Public Comment at Stakeholder Council Meeting

1. Derek Flowers, Value of Care Coalition
    - Upper Payment Limits are meant to be one tool of many, non-UPL options may be more important;
    - There is no timeline framework or progress for non-UPL tools, while the Board continues moving forward with UPL frameworks
    - policies identified by board were different from those sent to the legislature
    - The Value of Care Coalition requests that board be required to pursue non-UPL tools before pursuing UPLs

Policy Review Process - Information Gathering
Stakeholder Council Input - Summary

Circumstance #1 - Trulicity WAC Price increased faster than inflation

- Proposed Driver: WAC inflation may be due to systemic issues: Deron Johnson (Brand Name Corporations) commented that WAC price increases may be driven by inflationary pressures, lifecycle management or other factors that influence price; the Board should not act on WAC price increases unless it understands what caused the increase.

Policy Review Process - Information Gathering
Stakeholder Council Input - Summary

Circumstance #2 and #3 - Total gross spending for Ozempic for state and local governments exceeds 4.87% of gross prescription drug spend for state and local governments. Total gross spending for Trulicity for state and local governments exceeds 2.27% of gross prescription drug spend for state and local governments.

- Proposed Driver, Increased Use due to Clinical Efficacy: Dr. John Gambrill (public member), James Gutman (public member), Dr. Sherita Golden (Clinical Researchers), Dr. Sean Tunis (Health Services Researcher Specializing in Prescription Drugs) commented that these drugs are highly effective and have indications for high-cost conditions, and are recommended as best in class in diabetes clinical practice guidelines. Deron Johnson (Brand Name Corporations) commented that increased gross spend arises from increased utilization because the drugs are life-saving for many people.

Policy Review Process - Information Gathering
Stakeholder Council Input - Summary

Circumstance #1 and #2 - Total gross spending for Ozempic for state and local governments exceeds 4.87% of gross prescription drug spend for state and local governments. Total gross spending for Trulicity for state and local governments exceeds 2.27% of gross prescription drug spend for state and local governments.

- Proposed Driver, Off-Label Use: Dr. Mandi Poplawski (Nonprofit Insurance Carriers) commented that Ozempic has increased utilization through for weight loss among patients without type 2 diabetes, which may drive up costs and reduce access for those who want to use the medication in compliance with FDA-approved indications
- Proposed Driver, National Advertising: Dr. John Gambrill (public member) commented that drug advertisements raise patient awareness of these medications, contributing to increased utilization

Policy Review Process - Information Gathering
Stakeholder Council Input - Summary

Other Comments

- Deron Johnson commented that WAC price increases may be driven by systemic issues such as inflationary pressures, lifecycle management, or other factors that influence price; the Board should not act on WAC price increases unless it understands what caused the increase.
- Deron Johnson commented that generic entry could reduce utilization
- Dr. Mandi Poplawski commented that the Board could act to help ensure these medications are used in accordance with FDA-approved indications.
- Dr. Sean Tunis asked about the probability of negative impacts from UPLs, including how the Board would monitor for negative effects.
- Kelly Schultz (Biotechnology Companies) was interested in DTC pricing and how that might impact the decision of whether to impose a UPL
- Dr. Sherita Golden commented that some competitors to Trulicity offer similar benefits plus additional weight loss

Policy Review Process - Information Gathering COMAR 14.01.05.04(D)(4)- Board Staff Research and Analysis

Board Staff Research and Analysis.

(a) Board staff may provide the Board with policy research and analyses related to the drivers of the potential affordability and potential options.

(b) Research may include a literature review of available literature and original quantitative or qualitative research conducted by staff.

COMAR 14.01.05.04(D)(4)

Policy Review Process - Information Gathering COMAR 14.01.05.04(D)(4)- Board Staff Research and Analysis

Board Staff Research and Analysis.

- Staff conducted a literature review and a review of policies proposed or implemented by other entities or jurisdictions to inform potential policy options
- The current literature and policy reviews included:
  - Reviewed 7 federal and state policies, including policies of CMS, Connecticut, and other states
  - Reviewed 20 papers published in academic journals

Policy Review Process - Information Gathering COMAR 14.01.05.04(D)(5)- Eligible Governmental Entities' Information.

Eligible Governmental Entities' Information.

(a) Board staff may collect information concerning the prescription drug product and therapeutic alternatives from eligible governmental entities.

(b) The information collected may include utilization, spending, costs, benefit design, formulary placement, rebates, discounts, price concessions and other relevant information.

Policy Review Process - Information Gathering COMAR 14.01.05.04(D)(5)- Eligible Governmental Entities' Information.

Eligible Governmental Entities' Information.

- Staff has requested information from select governmental entities and is in the processing of requesting information from other governmental entities
- Information is primarily confirmational
- Eligible Governmental Entities currently working to respond
- Certain Eligible Governmental Entities have indicated that key information, such as net spend for each drug, is not available to them

Preliminary Policy Recommendations for Further Development, Analysis and Consideration

Analysis Underpinning Policy Recommendations

When recommending policy options (both UPL and non-UPL), Board staff may analyze the:

(a) Drivers of the affordability challenge;

(b) How the policy addresses a driver;

(c) Strengths and weaknesses of the policy;

(d) Possible implementation of the policy through legislation, regulation, or enforcement; and

(e) Potential impacts of the policy.

When recommending a UPL, Board staff may also consider:

(f) Relevant regulatory criteria under Regulation .02 of this chapter; and

(g) Use of the drug by eligible governmental entities.

COMAR 14.01.05.05B and C.

Circumstances to Map to Drivers

The circumstances under which the prescription drug products have led to affordability challenges include:

1. the percentage change in Trulicity wholesale acquisition cost (WAC) (list price) over time is substantially larger than the percentage change in inflation (rate of increase in inflation);
2. total gross spending for Trulicity for state and local governments exceeds 2.27% of gross prescription drug spend for state and local governments; and
3. total gross spending for Ozempic for state and local governments exceeds 4.87% of gross prescription drug spend for state and local governments.

Driver 1.1 (Trulicity): Incentive to Maximize Rebates Instead of Minimizing Net Costs

- Manufacturers and PBMS negotiate drug rebates. Some PBM contracts with payors provide for compensation of the PBM based on those rebates.
- Under some contracts, PBMs are paid a portion of those rebates, and may have a financial incentive to prefer the drug with a larger rebate over the drug with the lowest net cost.
- An increase in list price (WAC) allows rebate amounts to increase without lowering the net cost.
- To effect an increase in rebates, manufacturers historically have increased the list price (WAC) rather than reduced the net cost. This demonstrates an exercise of market power.

NOTE: An increasing list price (WAC) may directly impact patients by influencing patient cost sharing.

Driver 1.2 (Trulicity): Increased List Prices (WAC) Gives Manufacturers More Leverage in Negotiations

- Increasing list prices (WAC) puts pressure on insurer to negotiate or face increased costs to insurers and patients.
- Increasing list price (WAC) maximizes manufacturers profits, irrespective of whether the manufacturer has negotiated a rebate with the insurer.

Drivers 2.1 (Trulicity) and 3.1 (Ozempic): Gross Spending is High Because these Drugs have High Utilization

- These drugs have a special place in therapy for treating patients with comorbidities, which represents a large portion of patients with diabetes
- Gross spend is high in part because there are a large number of users (*i.e.*, high utilization) and the drug has a high price (*i.e.*, high cost)
- In the case of these drugs, the price is high on both a list and net basis, so high gross spend is associated with a high net spend

Driver 3.2 (Ozempic): Gross Spending May be Impacted By Off-label Use

- Information was developed through the Information Gathering process suggesting widespread off-label use of semaglutide for weight loss.
- Nationally, the number of Ozempic users with a documented diabetes diagnosis fell from 91% in 2019 to 63% in 2022.[1]
- However, staff confirmed that Ozempic utilization through the state employee benefit plan and some local government employee benefit plans is consistent with FDA label indications (*e.g.*, diabetes) rather than off-label uses.

1. Gordon AC. Off-label use of Semaglutides Continued to Grow in 2022 for those with Employer-Sponsored Insurance. Health Care Cost Institute. April 1, 2025. https://healthcostinstitute.org/all-hcci-reports/off-label-use-of-semaglutides-continued-to-grow-in-2022-for-those-with-employer-sponsored-insurance/

Preliminary Policy Recommendations

Summary of Previous Policy Recommendations Explored by the Board (Farxiga and Jardiance)

- WAC Inflation Penalty
- PBM Compensation
  - Delinking PBM Compensation from Rebates
    - Flat Rate
  - Delinking PBM Compensation from WAC Increases
    - Compensation Based on WAC in Time

WAC Inflation Penalty

Policy Explanation

- Manufacturers would pay a penalty on the gross Maryland revenue attributable to the increase in WAC above inflation

WAC Inflation Penalty- Strengths and Weaknesses

Strengths:

- Directly provides a disincentive to engage in WAC price increases
- Fairly easy to implement
- May generate revenue for the State

Weaknesses:

- Prior research suggests other inflation penalties (*e.g.*, Medicaid inflation penalty) have limited impact or no impact overall on WAC increases

WAC Inflation Penalty- Potential Impact

Potential Impact

- The policy is expected to either raise revenue for the State but not fully curb WAC increases, or curb WAC increases without raising revenue.

WAC Inflation Penalty- Implementation

Legislation and supporting regulations as applicable.

WAC Inflation Penalty- Drivers

Drivers

- This policy addresses multiple drivers, primarily drivers 1.1 and 1.2.
- This policy provides a counter-pressure to the existing pressure to increase WAC prices. Drivers 1.1 and 1.2 explain the incentive to increase WAC. An inflation penalty provides an incentive to prevent WAC increases.

PBM Compensation
Delinking PBM Compensation from Rebates or from WAC Increases

Policy Explanation

- PBMs are often paid based on a percentage of the rebates they negotiate, which provides an incentive for preferring drugs with a higher list price (WAC) and larger rebate amount.
- Delinking PBM Compensation from Rebates
    - PBM compensated based on negotiated flat rate rather than rebates
- Delinking PBM Compensation from WAC Increases
    - Compensation Based on WAC in Time. This policy would set a specified WAC and the compensation would be derived from the difference between the net price and the specified WAC.

PBM Compensation- Strengths and Weaknesses

- Strengths
  - Removes pressure for manufacturers to increases list prices for the purposes of being able to compete on rebate (as opposed to net price)
  - Reduces the incentive for PBMs to prefer high list price products
- Weaknesses
  - Flat fee may remove incentives for PBMs to negotiate more aggressively, and may increase net cost
  - Rebate reimbursement based on fixed WACs may encourage higher launch prices

PBM Compensation- Potential Impact

Potential Impact:

- One study suggests delinking compensation from the list price of a drug removes the incentive to favor high-cost, high-rebate drugs and could lower overall drug spending by about 15%[1]
  - This study looks across the entire supply chain and may not reflect experience at the plan sponsor level

1. Joyce G. The cost of misaligned incentives in the pharmaceutical supply chain. Health Aff Sch. 2025;3(7):qxaf126. Published 2025 Jun 25. doi:10.1093/haschl/qxaf126

PBM Compensation- Implementation

Legislation and supporting regulations as applicable.

PBM Compensation- Drivers

- This policy addresses multiple identified drivers, primarily 1.1 and 1.2
- Delinking PBM compensation from rebates reduces the pressures on PBMs to prefer drugs with higher WAC
- Delinking PBM compensation from WAC reduces the pressures on manufacturers to increase the WAC.

Staff Recommendations for Other Non-UPL Policy Actions (Trulicity and Ozempic)

- Bulk Purchasing/Subscription Model (Both)
- State Generic Manufacturing (Ozempic)
- State Participation in CMMI models (Both)
- Plan Design and PBM Reform Study and Recommendations (Both)
- GLP-1 Study and Recommendations (Both)

Bulk Purchasing/Subscription Model

Policy Explanation

- State would enter into a modified subscription agreement where the State pays a capped negotiated fee/agreement to a single manufacturer for a supply of Ozempic medication for Medicaid, State Employee, and/or other Maryland populations.

Bulk Purchasing/Subscription Model- Strengths and Weaknesses

Strengths:

- Budget predictability
- Expanded clinical access
- Prevention of downstream costs

Weaknesses:

- Model has been used for curative treatments; however, applying it to chronic treatments may create an indefinite financial commitment for the state and manufacturer
- High discontinuation rates disrupting population predictions, financial waste
- Supply chain and exclusivity risks due to singular manufacturer

Bulk Purchasing/Subscription Model- Potential Impact

Potential Impact:

- The policy is expected to either:
  - stabilize State budget predictability with the potential to overpay for non-adherent patients, or
  - lower the net price per treated patient while increasing the total long-term access and affordability of the State.

Bulk Purchasing/Subscription Model- Implementation

Legislation and supporting regulations as applicable

Bulk Purchasing/Subscription Model- Drivers

Drivers

- This policy addresses drivers 2.1 and 3.1 (High Utilization for Trulicity and Ozempic) and 3.2 (High Off-Label Utilization for Ozempic).
- This policy acts as a budgetary ceiling that offsets the financial impact of high utilization. While Drivers 2.1, 3.1, and 3.2 describe how increasing patient volume and high unit costs typically drive total spend upward, the subscription model decouples spending from volume, allowing the state to treat a large population of patients while managing total expenditures.

State Generic Manufacturing

Policy Explanation

- State could petition the federal government, under 28 U.S.C. § 1498, for authority to manufacturer generic Ozempic (semaglutide) for the state's Medicaid program and certain other programs.
- For example, Connecticut passed legislation in 2025 (Law Bill 1421) to mandate the Commissioner of Social Services to petition the Secretary of the Department of Health and Human Services to authorize generic forms of glucagon-like peptide 6 (GLP-1) prescription drugs approved by the FDA to treat obesity or diabetes. Upon petition approval, the Commissioner shall enter into a contract with a generic manufacturer to supply such drugs to the state for use by Medicaid.

State Generic Manufacturing- Strengths and Weaknesses

Strengths:

- Substantial price reduction for State purchasers
- Increased access for eligible patients due to reduced cost barriers
- Legal immunity for generic manufacturers by shifting legal liability to the government

Weaknesses:

- Federal dependence, requires approval and action from the federal HHS Secretary
- Compensation liability, which is determined by the courts
- Manufacturing lag, difficulties scaling FDA-approved generic production

State Generic Manufacturing- Potential Impact

Potential Impact

- The policy is expected to significantly reduce the per-unit cost of Ozempic through generic entry.

State Generic Manufacturing- Implementation

Legislation and supporting regulations as applicable.

State Generic Manufacturing- Drivers

Drivers

- This policy addresses drivers 3.1, and 3.2.
- This policy acts as a structural bypass of the existing pricing model by introducing immediate generic competition for Ozempic. While Drivers 3.1, and 3.2 explain how high utilization and high list prices drive total spend upward, state-authorized manufacturing directly targets the unit cost, providing the state with a supply of medication at near-production prices regardless of the manufacturer's Wholesale Acquisition Cost (WAC).

State Participation in CMMI Models

Policy Explanation

- State of Maryland to explore participation in new Centers for Medicare and Medicaid Innovation (CMMI) models that use international price benchmarking
  - BALANCE (Better Approaches to Lifestyle and Nutrition for Comprehensive hEalth) Model
    - Offers participating states access to MFN pricing to bulk purchase GLP-1s for their Medicaid and Medicare patients, along with access to lifestyle interventions.
  - GENEROUS (GENErating cost Reductions fOr U.S. Medicaid) Model
    - Most-Favored-Nation (MFN) pricing in Medicaid by inviting manufacturers to voluntarily provide supplemental rebates that achieve MFN-level prices for Covered Outpatient Drugs (CODs), while participating states apply standardized and transparent coverage criteria for modeled drugs.

State Participation in CMMI Models- Strengths and Weaknesses

Strengths:

- Cost savings from access to international pricing
- Standardized eligibility

Weaknesses:

- Reliant on voluntary participation from manufacturers
- States cannot combine MFN savings with their existing state-negotiated supplemental rebates
- Standardized Coverage Trade-offs, to participate Maryland must adopt "standardized coverage criteria" set by CMS, which doesn't allow the state to use its own Preferred Drug List (PDL) strategy
- Program is limited to Medicaid population

State Participation in CMMI Models- Potential Impact

Potential Impact

- The policy is expected to expand access and long-term effectiveness of Ozempic in Maryland by securing international-level pricing and integrated lifestyle supports.

State Participation in CMMI Models- Implementation

Legislation and supporting regulations as applicable.

State Participation in CMMI Models- Drivers

Drivers

- This policy addresses drivers 2.1, 3.1, and 3.2.
- This policy reduces cost by indexing drug cost to international benchmarks. While Drivers 2.1, 3.1, and 3.2 describe how high utilization and U.S. list prices drive total spend upward, these models directly reduce the unit price.

Plan Design and PBM Reform Study and Recommendations

Policy Explanation

- In collaboration with State and Stakeholder partners, Board studies key topics related to plan design and pharmacy benefit manager (PBM) practices and provides recommendations for the next Legislative Session, as applicable.

Plan Design and PBM Reform Study and Recommendations- Strengths and Weaknesses

Strengths:

- Allows for comprehensive review and consideration of issues related to plan design and pharmacy benefits

Weaknesses:

- The process of conducting the study may delay policies that could have been implemented in 2026
- Resource intensive
- Plan design and PBM business practices are so complex that there may not be clear policy solutions and recommendations at the end of the study

Plan Design and PBM Reform Study and Recommendations- Potential Impact

Potential Impact

- The policy is expected to establish a robust, data-driven roadmap of issues and recommended policy solutions related to plan design and PBM practices in 2027.

Plan Design and PBM Reform Study and Recommendations- Implementation

Study with policy recommendations to be implemented through legislation and supporting regulations as applicable.

Plan Design and PBM Reform Study and Recommendations- Drivers

Drivers

- This policy addresses driver 1.1 (Incentive to Maximize Rebates).
- This policy acts as an evidence-based foundation for future supply chain oversight. While Driver 1.1 describe how PBMs are incentivized to prefer high-WAC drugs to maximize rebate retention, this study allows the Board to examine these topics comprehensively to recommend plan design and PBM reform policies in a subsequent legislative session.

GLP-1 Study and Recommendations

Policy Explanation

- In collaboration with State and Stakeholder partners, Board conducts a class-wide, comprehensive assessment of GLP-1s. This study would examine issues related to access and affordability for Marylanders and provide formal policy recommendations for subsequent Legislative Sessions.

GLP-1 Study and Recommendations - Strengths and Weaknesses

Strengths:

- Allows for comprehensive review related to GLP-1s and existing context and policies, especially related to non-diabetes usage
- Evidence produced can address class-wide issues

Weaknesses:

- The process of conducting the study may delay policies that could have been implemented in 2026
- Resource intensive
- Issues related to GLP-1s may be so complex that there may not be clear policy solutions and recommendations at the end of the study

GLP-1 Study and Recommendations- Potential Impact

Potential Impact

- This policy is expected to establish a unified affordability framework for the entire GLP-1 class

GLP-1 Study and Recommendations - Implementation

Study with policy recommendations to be implemented through legislation and supporting regulations as applicable.

GLP-1 Report/Workgroup - Drivers

Drivers

- This policy addresses drivers 2.1, 3.1, and 3.2.
- Drivers 2.1, 3.1, and 3.2 describes how prescribing within established medical practice can inflate drug costs and gross spending; a class-wide review of GLP-1 medications would allow the Board to evaluate the market impact of these broader uses and recommend evidence-based policies that prioritize access and affordability

Preliminary Policy Recommendations - Upper Payment Limit (UPL)

Upper Payment Limit- Ozempic

Policy Explanation

- The PDAB may uses its current authority to establish UPLs for certain state and local government entities. These UPLs would limit the final net amount State and local governments pay for the prescription drug.

Upper Payment Limit - Ozempic - Strengths and Weaknesses

Strength:

- Ensures that affected entities' net costs are protected from WAC increases

Weaknesses:

- The mechanism of upper payment limits is indirectly related to manufacturer decisions to increase WAC prices
- Impact of savings to State and local governments is based on the net price that the entity is currently paying, and the UPL amount
- GLP-1s are subject to multiple national and state efforts to promote affordability and access

Upper Payment Limit - Ozempic - Implementation

UPLs will be implemented through rulemaking (regulations) published by the PDAB, that include:

- a specified UPL amount for specified eligible governmental entities; and
- the prospective effective date of implementation

Upper Payment Limit- Ozempic - Drivers

- UPLs address driver 3.1 (high gross spend from high price) and 3.2 (high utilization).
- Due to these drivers, State and local governmental entities have employed certain utilization management tools for Ozempic (*e.g.*, prior authorization, quantity limitations).
- A UPL reduces the amount paid by state and local government payers for these drugs, which allows the allocation of those resources to other needs and uses

Upper Payment Limit - Ozempic - (f) Relevant regulatory criteria under Regulation .02

B. The Board shall:

(1) Consider the cost of administering the drug and delivering the drug to consumers, as well as other relevant administrative costs;

(2) Determine whether an upper payment limit is an appropriate tool to address the drivers of the affordability challenge identified for the prescription drug product;

(3) Set an upper payment limit in a way to minimize adverse outcomes and minimize the risk of unintended consequences; and

(4) Prioritize drugs that have a high proportion of out-of-pocket costs compared to the system net cost of the drug.

Upper Payment Limit - Ozempic - (f) Relevant regulatory criteria under Regulation .02

C. The Board shall not set an upper payment limit if:

(1) Spending on the prescription drug product by the eligible governmental entities is less than the administrative cost to implement an upper payment limit; or

(2) The prescription drug product is a generic and there are nine or more marketed therapeutic equivalents for the product.

D. The Board shall not set an upper payment limit at an amount that:

(1) Impacts statutory or regulatory amounts, such as Medicaid Best Price; or

(2) Is lower than the Medicare Maximum Fair Price.

Upper Payment Limit - Ozempic - (g) Use of the drug by eligible governmental entities.

Table 9b. Ozempic Spending and Utilization

National Drug Code (11-Digit)	Proprietary Name	Dosage Strength	State Local Gov. Emp. (2023) Gross Spending	State Local Gov. Emp. (2023) Patient Count	State Local Gov. Emp. (2023) Pct Total Gross Spend
00169-4132-12	Ozempic	2 MG/1.5 ML	$2,653,728.00	1,275	0.3870%
00169-4181-13	Ozempic	2 MG/3 ML	$10,774,847.00	3,129	1.5712%
00169-4130-13	Ozempic	4 MG/3 ML	$12,857,706.00	2,796	1.8750%
00169-4130-01	Ozempic	4 MG/3 ML	$26,267.00	11	0.0038%
00169-4772-12	Ozempic	8 MG/3 ML	$7,085,183.00	1,345	1.0332%
00169-4132-11	Ozempic	2 MG/1.5 ML	***	***	***
00169-4136-02	Ozempic	2 MG/1.5 ML	***	***	***
50090-6051-00	Ozempic	8 MG/3 ML	***	***	***
00169-4772-11	Ozempic	8 MG/3 ML	***	***	***
00169-4136-11	Ozempic	2 MG/1.5 ML			
50090-5949-00	Ozempic	4 MG/3 ML	***	***	***

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Upper Payment Limit - Ozempic - (g) Use of the drug by eligible governmental entities.

Table 9c. Ozempic Spending and Utilization

National Drug Code (11-Digit)	Proprietary Name	Dosage Strength	Medicaid (2022) Gross Spending	Medicaid (2022) Patient Count	Medicaid (2022) Pct Total Gross Spend
00169-4132-12	Ozempic	2 MG/1.5 ML	$22,923,445.90	5,998	1.2525%
00169-4181-13	Ozempic	2 MG/3 ML			
00169-4130-13	Ozempic	4 MG/3 ML	$18,189,313.12	3,630	0.9938%
00169-4130-01	Ozempic	4 MG/3 ML	$47,805.01	18	0.0026%
00169-4772-12	Ozempic	8 MG/3 ML	$2,081,087.21	808	0.1137%
00169-4132-11	Ozempic	2 MG/1.5 ML	$104,064.17	52	0.0057%
00169-4136-02	Ozempic	2 MG/1.5 ML	$168,007.28	75	0.0092%
50090-6051-00	Ozempic	8 MG/3 ML			
00169-4772-11	Ozempic	8 MG/3 ML	$22,746.06	12	0.0012%
00169-4136-11	Ozempic	2 MG/1.5 ML	***	***	***
50090-5949-00	Ozempic	4 MG/3 ML	***	***	***

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Upper Payment Limit - Trulicity

Policy Explanation

- The PDAB may uses its current authority to establish UPLs for certain state and local government entities. A UPL would limit the final net amount state and local governments pay for the drugs.

Upper Payment Limit - Trulicity - Strengths and Weaknesses

Strength:

- Ensures that affected entities' net costs are protected from WAC increases

Weaknesses:

- The mechanism of upper payment limits is indirectly related to manufacturer decisions to increase WAC prices
- Impact of the savings to the state is based on the net price that the entity is currently paying, and the UPL amount
- Staff research and public comments suggest that Trulicity may have biosimilar competition as soon as 2027
- GLP-1s are subject to multiple national and state efforts to promote affordability and access

Upper Payment Limit - Trulicity - Implementation

UPLs will be implemented through regulation, that includes:

- a specified UPL amount;
- The eligible governmental entities that will be subject to the upper payment limit and the prospective effective date for each eligible governmental entity

Upper Payment Limit - Trulicity - Drivers

- UPLs address drivers 1.1 (Incentive to Maximize Rebates) and 1.2 (Increased Leverage from High WAC Prices).
- UPLs limit the effect of the WAC increase (list prices) on certain state and local governmental entities by establishing a ceiling net price that is not contingent on WAC increases.

Upper Payment Limit - Trulicity - (f) Relevant regulatory criteria under Regulation .02

B. The Board shall:

(1) Consider the cost of administering the drug and delivering the drug to consumers, as well as other relevant administrative costs;

(2) Determine whether an upper payment limit is an appropriate tool to address the drivers of the affordability challenge identified for the prescription drug product;

(3) Set an upper payment limit in a way to minimize adverse outcomes and minimize the risk of unintended consequences; and

(4) Prioritize drugs that have a high proportion of out-of-pocket costs compared to the system net cost of the drug.

Upper Payment Limit - Trulicity - (f) Relevant regulatory criteria under Regulation .02

C. The Board shall not set an upper payment limit if:

(1) Spending on the prescription drug product by the eligible governmental entities is less than the administrative cost to implement an upper payment limit; or

(2) The prescription drug product is a generic and there are nine or more marketed therapeutic equivalents for the product.

D. The Board shall not set an upper payment limit at an amount that:

(1) Impacts statutory or regulatory amounts, such as Medicaid Best Price; or

(2) Is lower than the Medicare Maximum Fair Price.

Upper Payment Limit - Trulicity - (g) Use of the drug by eligible governmental entities.

Table 7b. Trulicity Spending and Utilization

National Drug Code (11-Digit)	Proprietary Name	Dosage Strength	State Local Gov. Emp. (2023) Gross Spending	State Local Gov. Emp. (2023) Patient Count	State Local Gov. Emp. (2023) Pct Total Gross Spend
00002-1433-80	Trulicity	0.75 MG/0.5 ML	$4,005,661.00	823	0.5841%
00002-1434-80	Trulicity	1.5 MG/0.5 ML	$5,619,443.00	1,086	0.8194%
00002-2236-01	Trulicity	3 MG/0.5 ML			
00002-2236-80	Trulicity	3 MG/0.5 ML	$3,880,098.00	682	0.5658%
00002-3182-80	Trulicity	4.5 MG/0.5 ML	$2,040,785.00	319	0.2976%
00002-1433-01	Trulicity	0.75 MG/0.5 ML	***	***	***
00002-1434-01	Trulicity	1.5 MG/0.5 ML	***	***	***
00002-3182-01	Trulicity	4.5 MG/0.5 ML			
50090-3484-00	Trulicity	0.75 MG/0.5 ML	***	***	***
50090-6456-00	Trulicity	1.5 MG/0.5 ML	***	***	***
50090-3483-00	Trulicity	1.5 MG/0.5 ML	***	***	***
50090-6571-00	Trulicity	3 MG/0.5 ML	***	***	***
50090-5467-00	Trulicity	3 MG/0.5 ML	***	***	***

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Upper Payment Limit - Trulicity -
(g) Use of the drug by eligible governmental entities.

Table 7c. Trulicity Spending and Utilization

National Drug Code (11-Digit)	Proprietary Name	Dosage Strength	Medicaid (2022) Gross Spending	Medicaid (2022) Patient Count	Medicaid (2022) Pct Total Gross Spend
00002-1433-80	Trulicity	0.75 MG/0.5 ML	$15,485,519.87	3,838	0.8461%
00002-1434-80	Trulicity	1.5 MG/0.5 ML	$19,361,612.57	3,872	1.0578%
00002-2236-01	Trulicity	3 MG/0.5 ML	$40,222.69	13	0.0022%
00002-2236-80	Trulicity	3 MG/0.5 ML	$8,954,803.64	1,866	0.4893%
00002-3182-80	Trulicity	4.5 MG/0.5 ML	$4,032,667.02	741	0.2203%
00002-1433-01	Trulicity	0.75 MG/0.5 ML	$86,766.61	30	0.0047%
00002-1434-01	Trulicity	1.5 MG/0.5 ML	$90,068.85	26	0.0049%
00002-3182-01	Trulicity	4.5 MG/0.5 ML	***	***	***
50090-3484-00	Trulicity	0.75 MG/0.5 ML			
50090-6456-00	Trulicity	1.5 MG/0.5 ML			
50090-3483-00	Trulicity	1.5 MG/0.5 ML			
50090-6571-00	Trulicity	3 MG/0.5 ML			
50090-5467-00	Trulicity	3 MG/0.5ML	***	***	***

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Staff Guidance

Staff requests guidance and direction from the Board concerning which, if any, of the policies identified in the presentation should be further developed for the Board's consideration.

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