Cost Review Study Process
Preliminary Policy Recommendations

Updated and Revised September 24, 2025

PDAB Meeting

September 29, 2025

Andrew York, Executive Director

Program

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

COMAR 14.01.04.05A- Cost Review Study

July 28, 2025 Board Meeting. The Board had the opportunity to examine:

(1) Whether use of each drug, Jardiance and Farxiga, 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.

14.01.04.05.F Preliminary Determinations
July 28, 2025 Meeting

The Board made two preliminary determinations that the use of Farxiga and Jardiance have each created an affordability challenge for the State health care system.

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

1. the percentage change in wholesale acquisition cost (WAC) (list price) over time is substantially larger than the percentage change in inflation (rate of increase in inflation) (both drugs);
2. at the 90 percentile, patient out-of-pocket (OOP) costs in certain markets is disproportionate to the net cost paid by payors (both drugs);
3. total gross spending for Farxiga for state and local governments exceeds 1% of gross prescription drug spend for state and local governments; and
4. total gross spending for Jardiance for state and local governments exceeds 1.8% of gross prescription drug spend for state and local governments.

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 Jardiance and Farxiga 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.

Informational Hearing (at 1:00 pm)

- September 3, 2025 at 1:00 PM
  - 4 persons: Len Lucchi, Rev. Dr. Sandra Conner, George Huntley, Ranier Simons
  - Exhibit 1: The Notice of Informational Hearing
  - Exhibit 2: written materials (17 pages), George Huntley, Diabetes Patient Advocacy Coalition
  - Exhibit 3: Patient Jacquean Kosh
  - Exhibit 4: MedChi
  - Exhibit 5: Partnership to Advance Cardiovascular Health
  - Exhibit 6: Boehringer Ingelheim Pharmaceuticals
  - Exhibit 7: Jonas Nguh, PhD, RN, Immediate Past President Md Public Health Ass'n
  - Exhibit 8: Dr. Irance Reddix, Family Medicine Physician, Windsor Mill, Maryland
  - Exhibit 9: Candace DeMatteis, Partnership to Fight Chronic Disease in consult with Avalere Health

Informational Hearing (continued at 6:00 pm)

- September 3, 2025 at 6:00 PM
  - 1 person: Tiffany Westerich-Robertson, Ensuring Access Through Collaborative Health (EACH) Coalition Lead
  - Exhibit 10A: Ensuring Access Through Collaborative Health: Policy Brief
  - Exhibit 10B: Ensuring Access Through Collaborative Health: Patient Experience Survey: Prescription Drug Affordability and Unaffordability

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 the following:
  - Diabetes Advocacy Coalition
  - EACH/PIC Coalition (Two Submissions)
  - Value of Care Coalition
- Comment received after deadline (close of business Wednesday, August 20, 2025):
  - AbbVie (directed to Board)

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

Summary Public Comment at Stakeholder Council Meeting

1. George Huntley, Diabetes Patient Advocacy Coalition

- Emphasized that Jardiance and Farxiga are essential therapies and restricting access would increase complications and raise hospitalization costs
- Recommended against relying on UPLs, which may unintentionally disrupt manufacturer contracts with PBMs leading to higher copays, restrictive prior authorizations, and formulary exclusions
- Encouraged recommendation of patient-focused non-UPL solutions
- Insurers and PBMs to pass negotiated savings to patients in the form of rebates, concessions at the pharmacy counter to cut the out-of-pocket costs nearly in half
- Delink PBM reimbursement from drug prices to remove incentive for inflated prices

2. Tiffany Westrich-Robertson- EACH/PIC Coalition, Agenda Item 4

- Urged PDAB and PDASC to evaluate all available policy tools not simply move forward with a UPL
- Referenced report where patients stated that affordability challenges were rooted in evolving personal life situations, collective costs, and insurance barriers

Policy Review Process - Information Gathering
Stakeholder Council Input - Summary

Circumstance #1 - The percentage change in WAC (list price) over time is substantially larger than the percentage change in inflation (rate of increase in inflation) (both drugs).

- Deron Johnson (Brand Name Corporations), Shawn Brown (Generic Drug Corporations) and Dr. John Gambrill (Public Member): Driver is benefit design by insurers and market dynamics of PBMs. PBMs demand higher rebates for formulary placement, prompting manufacturers to raise list prices (WAC) to meet those demands. Policy solutions are passing rebates directly to patients or delinking PBM fees from drug prices to remove the incentive to favor high-cost, high-rebate drugs over lower-cost generics.
- Dr. Sean Tunis (Health Services Researcher Specializing in Prescription Drugs) and Glenn Schneider (Statewide Health Care Advocacy Coalition): A UPL creates an environment where currently unaffected manufacturers anticipate its impact and adjust their pricing strategies accordingly, while other entities respond to the initial price set. Although novel in the U.S., this approach has been implemented successfully in other countries.
- Dr. Danita Tolson (Statewide Organization for Diverse Communities): Establish an inflation penalty on the drug companies, or add to existing penalties.

Policy Review Process - Information Gathering
Stakeholder Council Input - Summary

Circumstance # 2 - At the 90 percentile, patient out of pocket (OOP) costs in certain markets is disproportionate to the net cost paid by payors (both drugs).

- Deron Johnson (Brand Name Drug Corporations) and Dr. Sherita Hill Golden (Clinical Researchers): Driver is insurers using accumulator programs and benefit design that shifts the cost onto the patient. Policy solutions are to support recently passed legislation to end this practice by ensuring all payments count towards patients' deductible, and changing plan design to offer first-dollar coverage.
- Deron Johnson (Brand Name Drug Corporations): The industry would support a deductible smoothing policy.

Policy Review Process - Information Gathering
Stakeholder Council Input - Summary

Circumstance #3 and #4: Total gross spending for Farxiga for state and local governments exceeds 1% of gross prescription drug spend for state and local governments. Total gross spending for Jardiance for state and local governments exceeds 1.8% of gross prescription drug spend for state and local governments.

- Dr. Sean Tunis (Health Services Researcher Specializing in Prescription Drugs) and Dr. Sherita Hill Golden (Clinical Researchers): Driver is that these drugs are highly effective, recommended in clinical practice guidelines, and address the high prevalence of diabetes in Maryland.

Policy Review Process - Information Gathering
Stakeholder Council Input - Summary

Other Drivers

- Dr. Sherita Hill Golden (Clinical Researchers) and Deron Johnson (Brand Name Drug Corporations): Driver is insurance benefit design (copays, coinsurance and deductibles), referencing EACH PIC patient survey where 100% cited insurance barriers and ¾ skipped dosage due to insurance delays.
- Glenn Schneider (Statewide Health Care Advocacy Coalition) and Kimberly Robinson (Pharmacy Benefit Managers): Drug costs originate with the manufacturer and ultimately impact all entities acquiring the drugs throughout the supply chain.

Policy Review Process - Information Gathering Stakeholder Council Input - Summary

Other Comments

- James Gutman (Public Member), Glenn Schneider (Statewide Health Care Advocacy Coalition), Dr. Sean Tunis (Health Services Researcher Specializing in Prescription Drugs) and Dr. Danita Tolson (Statewide Organization for Diverse Communities): The Board needs to consider the time it will take to develop alternative policies compared to UPLs, highlighting the urgency of the issue.
- Dr. Sean Tunis (Health Services Researcher Specializing in Prescription Drugs): As UPLs are not yet implemented, there's no evidence for unintended consequences. Also questioned why Maryland's negative outcomes would differ from national trends if these factors were taken into account during Medicare drug price negotiations for Jardiance and Farxiga.
- Shawn Brown (Generic Drug Corporations): The generic drug industry faces fixed PBM contracts that block price increases despite rising costs, contributing to shortages. The IRA creates long-term uncertainty for generics entering in 8–10 years, discouraging competition, which is more effective than price controls in lowering drug prices.
- Dr. Sherita Hill Golden (Clinical Researchers) and Deron Johnson (Brand Name Drug Corporations): A consistent and clear definition of affordability is needed.

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 11 federal and state policies, including policies of CMS, Kentucky, and other states
  - Reviewed 21 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 wholesale acquisition cost (WAC) (list price) over time is substantially larger than the percentage change in inflation (rate of increase in inflation) (both drugs);
2. at the 90 percentile, patient out-of-pocket (OOP) costs in certain markets is disproportionate to the net cost paid by payors (both drugs);
3. total gross spending for Farxiga for state and local governments exceeds 1% of gross prescription drug spend for state and local governments; and
4. total gross spending for Jardiance for state and local governments exceeds 1.8% of gross prescription drug spend for state and local governments.

Driver 1.1: 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.
- Because PBMs are paid a portion of those rebates, PBMs 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: 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.

Driver 2.1: Patients with high OOP costs are using drugs for which their health plan gets lower rebates than average and thus are non-preferred drugs

- Many insurance companies place drugs for which they have not reached an advantageous rebate agreement on higher formulary tiers. This often has the effect of incentivizing patients to use the preferred lower cost drug.
- For a variety of reasons, some patients continue to use the higher priced drug.
- As a result, a portion of the 90th percentile out-of-pocket costs reflect patients using a drug that is both expensive for them (OOP cost) and the insurer.

Driver 2.2: Patients with high OOP costs represent patients enrolled in high deductible plans

- High-deductible plans are plans in which patients must first pay their deductible (out-of-pocket cost) before the plan begins to pay
- In a high-deductible plan, the insurer/PBM receives rebates when a patient is paying the full cost of the drug in the deductible phase; thus, irrespective of who pays, the insurer/PBM receives the benefit of the rebate, not the patient
- Because patients' out-of-pocket costs are paid up front (until the deductible is met), the patient pays a disproportionate amount of the overall annual cost

Driver 2.3: Patients with high OOP costs represent patients enrolled in plans with high coinsurance rates

- Certain plans have high coinsurance rates for certain drugs.
- Coinsurance is often based on the list price of the drug (WAC), so a relatively low percentage of coinsurance can cause high out-of-pocket cost.
- As a result, patients often find themselves paying a large portion of the net costs.

Driver 3.1 and 4.1: 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 because there are a large number of users (*i.e.*, high utilization) and the drug has a high price (*i.e.*, high cost)

Preliminary Policy Recommendations

Policy Action Other than UPL
Staff Recommendations

- WAC Inflation Penalty
- Real Time Benefit Tool
- Patient Navigator Program
- 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.

Real-Time Benefit Tool

Policy Explanation

- Establish rules that require plans to adopt real-time benefit tools
- A Real-Time Benefit Tool is software integrated into electronic health records that allows patients and prescribers to access real-time formulary and benefit information, including cost-sharing, to shop for lower-cost alternative therapies under their prescription drug benefit plan

Real-Time Benefit Tool- Strengths and Weaknesses

Strengths:

- Builds on existing software and integrations developed for Medicare
- Gives patients the ability to make an informed choice about cost prior to picking up the drug at a pharmacy.

Weaknesses:

- Does not directly lower out-of-pocket costs; only lowers out-of-pocket costs if there is a cheaper alternative that the patient can take
- Operational complexity: requires integration between health plans, pharmacy switch providers, and EHR vendors

Real-Time Benefit Tool- Potential Impact

- Literature suggests a range of potential outcomes, though most are limited:
  - One study suggested that only 3% of prescriptions were changed as a result of the drug selection recommended by the tool.[1]
  - Another study suggested that 1.6% of prescriptions had a therapy recommendation with an average savings of almost $40.[2]
    - Only 5% of the suggested savings from the real-time benefit tool were used.
  - Another study suggested that the tool provided a recommendation for a lower cost alternative approximately 60% of the time, and prescribers followed the recommendation 32% of the time.[3]
    - When switched to the lower cost, the copays averaged $27 cheaper

1. Bhardwaj S, Miller SD, Bertram A, Smith K, Merrey J, Davison A. Implementation and cost validation of a real-time benefit tool. Am J Manag Care. 2022 Oct 1;28(10):e363-e369. doi: 10.37765/ajmc.2022.89254. PMID: 36252176.
2. Reise R, Ndai AM, Dewar MA, Schentrup AM, Yang J, Vouri SM. Assessment of the utilization of real-time prescription benefits for patient cost savings within an outpatient setting. Explor Res Clin Soc Pharm. 2024 Jun 5;14:100460. doi: 10.1016/j.rcsop.2024.100460. PMID: 38974055; PMCID: PMC11227025.
3. Fitts A, Teare AJ, Nelson SD. Price transparency at the point of prescribing with real-time prescription benefits. Am J Health Syst Pharm. 2024 Sep 23;81(19):e620-e626. doi: 10.1093/ajhp/zxae108. PMID: 38713809; PMCID: PMC11419340.

Real-Time Benefit Tool- Implementation

Legislation and supporting regulations as applicable

Real-Time Benefit Tool-Drivers

- This policy address multiple drivers, primarily 2.1, 2.2, and 2.3
- High out-of-pocket costs are understood to be largely driven by plan design, and Real-Time Benefit Tools help patients and prescribers navigate the patients' plan to use the therapies that are the most affordable for the patient

Patient Navigator Program

Policy Explanation

- 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.

Patient Navigator Program- Strengths and Weaknesses

Strengths:

- Utilizes existing patient assistance programs
- Builds on existing state resources, *e.g.*, Senior Prescription Drug Assistance Program (SPDAP) and Maryland 2-1-1 Program
- Strong return on investment;
- Directly address drivers 2.1, 2.2, and 2.3

Weaknesses:

- May exacerbate drivers 1.1 and 3.1. The Board should conduct additional analyses on the impacts of patient assistance programs and copay coupon programs for a more comprehensive policy related to patient assistance programs.

Patient Navigator Program- Impact

- Reports indicate that, for a cost of $600,000 per year[1] Kentucky supported over 6,000 patients with over 23,000 prescriptions Provided a total value to patients in excess of $53 million on their prescription drugs.[2]

1. Kentucky Prescription Assistance Program KPAP: The Small Program with a Big Impact. https://apps.legislature.ky.gov/CommitteeDocuments/7/20893/06%2002%202022%20KPAP%20Information.pdf

2. Team Kentucky Cabinet for Health and Family Services- Kentucky Fiscal Year 2024. https://www.chfs.ky.gov/agencies/os/codata/LegislativeReport_2024%20-%20State.pdf

Patient Navigator Program- Implementation

Legislation and supporting regulations as applicable

- The Kentucky Prescription Assistance Program (KPAP) was created through legislation that included funding
- Funding is necessary to develop and implement the program

Patient Navigator Program- Drivers

- This policy addresses the impact of drivers 2.1, 2.2, and 2.3.
- Patient assistance programs can help to reduce certain patient out-of-pocket costs for qualifying Maryland patients.

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- 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
- Delinking PBM compensation from WAC increases reduces the pressures on manufacturers to increase the WAC.

Policy Action in the Form of an Upper Payment Limit Staff Observations

Farxiga

- Upper Payment Limit for Certain Eligible Governmental Entities

Jardiance

- Upper Payment Limit for Certain Eligible Governmental Entities

Upper Payment Limit- Farxiga

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 government pay for the drugs.

Upper Payment Limit- Farxiga- 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 and to local governments is based on the net price that the entity is currently paying, and the UPL amount
- Staff research and public comments suggest that Farxiga may have generic competition as soon as April 4, 2026

Upper Payment Limit- Farxiga- Implementation

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

- a specified UPL amount for specified eligible governmental entities.
- the prospective effective date implementation

Upper Payment Limit- Farxiga- Drivers

- UPLs address drivers 1.1 and 1.2
- 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- Farxiga-
(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- Farxiga-
(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- Farxiga-
(g) Use of the drug by eligible governmental entities.

Table 10b. Farxiga 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
66993-0457-30	Farxiga	10 MG	$21,612.00	18	0.0032%
00310-6210-39	Farxiga	10 MG			
00310-6210-30	Farxiga	10 MG	$5,938,802.00	1,300	0.8660%
00310-6205-30	Farxiga	5 MG	$1,465,689.00	405	0.2137%
66993-0456-30	Farxiga	5 MG	***	***	***

*** This symbol indicates information suppressed in compliance with state and federal data use agreements and the applicable cell size suppression policy. This policy requires that no cell of ten (10) or less may be displayed and that no percentages or other mathematical formulas may be used in a document if based on a sample of ten (10) or fewer patients.

^^^This symbol indicates information redacted/suppressed as confidential, trade secret and proprietary information in compliance with Health-General Article §§ 21-2C-10 and 21-2C-03, and applicable data use and commercial licensing agreements. In some cases, calculated information is redacted because it can be used to calculate the proprietary data.

Blank spaces indicate that no data was provided.

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

Table 10c. Farxiga 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
66993-0457-30	Farxiga	10 MG			
00310-6210-39	Farxiga	10 MG			
00310-6210-30	Farxiga	10 MG	$3,165,622.96	949	0.1730%
00310-6205-30	Farxiga	5 MG	$930,075.01	334	0.0508%
66993-0456-30	Farxiga	5 MG			

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Blank spaces indicate that no data was provided.

Upper Payment Limit- Jardiance

Policy Explanation

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

Upper Payment Limit- Jardiance- 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 Jardiance may have generic competition as soon as October 15, 2027

Upper Payment Limit- Jardiance- Implementation

UPLs will be implemented through regulation, that include:

- 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- Jardiance- Drivers

- UPLs address drivers 1.1 and 1.2
- 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- Jardiance-
(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- Jardiance-
(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- Jaridiance-
(g) Use of the drug by eligible governmental entities.

Table 12b. Jardiance 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
00597-0152-90	Jardiance	10 MG	$897,155.00	253	0.1308%
00597-0152-30	Jardiance	10 MG	$4,629,223.00	1,199	0.6750%
00597-0153-90	Jardiance	25 MG	$1,699,246.00	683	0.2478%
00597-0153-30	Jardiance	25 MG	$5,578,432.00	1,417	0.8135%
71610-0177-45	Jardiance	25 MG			
00597-0153-37	Jardiance	25 MG	***	***	***
71610-0177-15	Jardiance	25 MG			
00597-0152-37	Jardiance	10 MG	***	***	***
71610-0177-42	Jardiance	25 MG	***	***	***

*** This symbol indicates information suppressed in compliance with state and federal data use agreements and the applicable cell size suppression policy. This policy requires that no cell of ten (10) or less may be displayed and that no percentages or other mathematical formulas may be used in a document if based on a sample of ten (10) or fewer patients.
^^^This symbol indicates information redacted/suppressed as confidential, trade secret and proprietary information in compliance with Health-General Article §§ 21-2C-10 and 21-2C-03, and applicable data use and commercial licensing agreements. In some cases, calculated information is redacted because it can be used to calculate the proprietary data.
Blank spaces indicate that no data was provided.

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

Table 12c. Jardiance 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
00597-0152-90	Jardiance	10 MG	$800,953.23	398	0.0438%
00597-0152-30	Jardiance	10 MG	$7,527,001.06	2,472	0.4112%
00597-0153-90	Jardiance	25 MG	$1,431,274.74	644	0.0782%
00597-0153-30	Jardiance	25 MG	$8,067,144.09	2,264	0.4408%
71610-0177-45	Jardiance	25 MG			
00597-0153-37	Jardiance	25 MG	$53,659.64	35	0.0029%
71610-0177-15	Jardiance	25 MG			
00597-0152-37	Jardiance	10 MG	***	***	***
71610-0177-42	Jardiance	25 MG			

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Blank spaces indicate that no data was provided.

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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