Health-General § 21-2C-09(c)
2024 Annual Report

Maryland Prescription Drug Affordability Board
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MARYLAND
Prescription Drug Affordability Board

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INTRODUCTION

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

KEY 2024 MARYLAND PRESCRIPTION DRUG AFFORDABILITY BOARD ACTIONS

Overview of Cost Review Study Process:

The Cost Review Study Process, as outlined in the Maryland Code of Regulations ("COMAR") 14.01.01, is a tool for the Board to study specific drugs to understand if the drug causes affordability challenges for Maryland patients or the state of Maryland. The outcome of the Cost Review Study Process is for the Board to "determine whether use of the prescription drug product that is fully consistent with the labeling approved by the United States Food and Drug Administration or standard medical practice has led or will lead to affordability challenges for the State health care system or high out-of-pocket costs for patients"[1] (i.e., causes affordability challenges). The Board made significant progress in 2024. A detailed timeline of Board actions is available in Appendix A.

The Board published the regulations establishing the Cost Review Study Process as COMAR 14.01.04 at the end of 2023, and began to implement its first Cost Review Study Process in early 2024. The Cost Review Study Process is made up of 5 overall phases: Identify, Select, Collect, Analyze, and Results.

Identify

The Cost Review Study process starts with the identification of drugs that are eligible for the Cost Review Study Process according to Health-General Article § 21-2C-08(c) and the additional criteria identified by the Board in COMAR 14.01.04.02.D. Next, the Board receives a dashboard with the eligible drugs and the relevant criteria outlined in COMAR 14.01.04.03 for selecting the drugs for the Cost Review Study process. The Board received the first dashboard in early 2024.

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

Select

Next, the Board must select a subset of drugs to the Prescription Drug Affordability Stakeholder Council (Stakeholder Council) that it is considering for selection for the Cost Review Study Process for public input and input from the Stakeholder Council. The Board referred 8 drugs to the Stakeholder Council for input in March 2024 (Biktarvy, Dupixent, Farxiga, Jardiance, Ozempic, Skyrizi, Trulicity, and Vyvanse).

The Board considered public and Stakeholder Council input and selected drugs for the Cost Review Study Process. The Board selected 6 drugs for the Cost Review Study Process in May 2024 (Dupixent, Farxiga, Jardiance, Ozempic, Skyrizi, and Trulicity).

Collect

Next, the Board collected the data necessary to conduct the Cost Review Study Process. One of the primary tools to collect these data is through the Request for Information (RFI), which collects data from manufacturers, wholesalers, payors, and pharmacy benefit managers that can support the Board in determining if drugs selected for the Cost Review Study Process may lead to affordability challenges. The Board conducted the Request for Information for 4 of the drugs selected for the Cost Review Study Process in July 2024 (Farxiga, Jardiance, Ozempic, and Trulicity). The RFI for the remaining 2 drugs will be conducted in late 2024 or early 2024.

Analyze

The Board analyzes the elements included in the Cost Review Study Process, as articulated in COMAR 14.01.04.06. The Board is currently conducting and drafting the document with the analyses and expects to publish these analyses in late 2024 or early 2025.

Results

Ultimately, the Board must determine if the drugs in the Cost Review Study Process led to an affordability challenge. The Board published proposed regulations on November 1, 2024 to update the Cost Review Study Process to account for the Policy Review Process outlined in the Upper Payment Limit Action Plan outlined below. The proposed regulations create a step for a "preliminary determination" of if a drug may lead to affordability challenges. If the Board makes the preliminary determination that a drug may lead to affordability challenges, then the Board can go through its Policy Review Process to identify and implement policies that may help make those drugs more affordable for patients and the state, including setting upper payment limits for state and local government. The Board expects to implement the Policy Review Process in late 2024 or early 2025.

Number of Prescription Drug Products that were Subject to Board Review:

The Board began its first series of Cost Reviews in 2024. In March 2024, the Board identified 8 drugs that represented affordability challenges (Biktarvy, Dupixent, Farxiga, Jardiance, Ozempic, Skyrizi, Trulicity, and Vyvanse) and referred them to the Prescription Drug Affordability Stakeholder Council for input.

After careful review, the Board selected 6 of those drugs for the Cost Review Study Process in the July 2024 Board meeting:

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

The Board recognized the resources required to analyze many drugs simultaneously and provided guidance to start by conducting the Request for Information (RFI) for Farxiga, Jardiance, Ozempic, and Trulicity. These 4 drugs are in the GLP-1 RA or SGLT2 inhibitor classes and treat type 2 diabetes. Since they are all anti-diabetic drugs, there are efficiencies in analyzing these similar types of drugs. The decision was made to subsequently conduct the RFI process for Dupixent and Skyrizi as resources and capacity permit. The Board issued the RFI for Farxiga, Jardiance, Ozempic, and Trulicity in July of 2024, and will likely issue the RFI for Dupixent and Skyrizi in early 2025.

Results from the 2024 Cost Review Study Process:

The Board has received information in response to the RFI for four drugs and is collecting additional information and data and conducting specified analyses in accordance with COMAR 14.01.04.05. The Board is continuing to conduct the Cost Review Study Process for the 6 drugs selected. The Board expects to make a preliminary determination on whether the drugs in the Cost Review Study Process may cause affordability challenges in late 2024 or early 2025. If the Board makes the preliminary determination that a drug may cause an affordability challenge, then it may begin the Policy Review Process, as outlined in the Upper Payment Limit Action Plan.[2]

[2] Mitchell, Van T. *Health General Article § 21-2C-13(d) - Prescription Drug Affordability Board - Upper Payment Limit Action Plan*. Maryland Prescription Drug Affordability Board. 10 Sept. 2024. Available at: https://pdab.maryland.gov/Documents/reports/Health%20General%20Article%20%c2%a7%2021-2C-13%28d%29-%20Prescription%20Drug%20Affordability%20Board-%20Upper%20Payment%20Limit%20Action%20Plan.pdf (Last accessed 18 Nov. 2024).

Upper Payment Limits and the Upper Payment Limit Action Plan

In accordance with § 21-2C-13, the Board published the Upper Payment Limit Action Plan,[3] which addresses "implementing the process that includes the criteria the Board shall use to set upper payment limits." The Board submitted the Upper Payment Limit Action Plan to the Legislative Policy Committee (LPC) in September 2024, and the Action Plan was approved by the LPC in October 2024.

The Board must put the process outlined in the Upper Payment Limit Action Plan into place by publishing regulations establishing the process. The Board has published draft regulations for public comment in October of 2024, and received 16 written comments in response. The Board will continue to work towards proposing the adoption of regulations establishing the UPL framework and may publish the regulations in late 2024 or early 2025.

2024 PRICE TRENDS FOR PRESCRIPTION DRUG PRODUCTS

National:

Overall U.S. spending growth on biopharmaceuticals decreased in 2023. Much of this reduction can be attributed to the declining utilization of COVID-19 vaccines and therapeutics.[4] When including COVID-19 vaccines and therapeutics, spending growth in the U.S. medicine market slowed to 2.5%.[5] This is below the rate of overall inflation. Total net spending was $435 billion.[6] However, when COVID-19 vaccines and therapeutics are excluded from the total, then spending growth increased to 9.9%.[7] Increases in biopharmaceutical spending for oncology, immunology, diabetes, and obesity drugs were responsible for most of the increase in 2023.[8]

The average out-of-pocket cost per retail prescription increased in 2023. For many drugs, the out-of-pocket spending was minimal. These are primarily generic drugs, which represent 90% of drugs dispensed. Out-of-pocket costs for patients were under $20 for 90% of all prescriptions that were filled.[9] Brand name drugs typically have much higher out-of-pocket costs and some

[3] *Id*.
[4] IQVIA Institute. *The Use of Medicines in the U.S. 2024: Usage and Spending Trends and Outlook to 2028.* 7 May 2024. Available at: https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/the-use-of-medicines-in-the-us-2024 (Last accessed 18 Nov. 2024).
[5] *Id*.
[6] *Id*.
[7] *Id*.
[8] *Id*.
[9] *Id*.

have relatively high out-of-pocket costs. In 1% of all prescriptions that were filled, or 71 million prescriptions, the out-of-pocket costs exceeded $125.[10]

Aggregate out-of-pocket costs for all patients increased by 6% in 2023. Out-of-pocket spending increased by $5 billion in 2023 to a total of $91 billion.[11] Biopharmaceutical companies provided $23 billion in manufacturer co-pay assistance programs that reduced the out-of-pocket costs to patients.[12] However, in spite of these coupons, the out-of-pocket costs still increased by 6%.

Americans filled more prescriptions in 2023 than they did in 2022. The number of new prescriptions rose by 3% in 2023.[13]

The prices set by the drug companies (list prices) increased by 4.9% in 2023.[14] This represents a slower growth than in prior years. One possible reason is that the Inflation Reduction Act (IRA) penalizes companies that raise prices faster than inflation.[15] Forecasting price increases in the future is difficult, but some forecasters have estimated that list price increases are expected to increase an average 1-4% per year between 2024 and 2028.[16] The rates of increase could depend on a number of factors for specific drugs.

One main concern is the prices for new brand name drugs entering the market with very high list prices. In 2023, biopharmaceutical companies "launched new U.S. drugs at prices 35% higher than in 2022, reflecting in part the industry's embrace of expensive therapies for rare diseases."[17] Over half of new product FDA approvals in 2023 and 2022 were for orphan diseases.[18] Orphan drugs are defined as drugs that treat diseases that affect fewer than 200,000 Americans.

[10] McNulty, Rose. *IQVIA Report Highlights Shifts in Medicine Use, Spending Across Therapy Areas.* AJMC. 10 May 2024. Available at: https://www.ajmc.com/view/iqvia-report-highlights-shifts-in-medicine-use-spending-across-therapy-areas (Last accessed 18 Nov. 2024).
[11] *Id*.
[12] *Id*.
[13] IQVIA Institute. *The Use of Medicines in the U.S. 2024: Usage and Spending Trends and Outlook to 2028.* 7 May 2024. Available at: https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/the-use-of-medicines-in-the-us-2024 (Last accessed 18 Nov. 2024).
[14] *Id*.
[15] *Id*.
[16] *Id*.
[17] Beasley, Deena. *Prices for new US drugs rose 35% in 2023, more than the previous year*. Reuters. 23 Feb. 2024. Available at: https://www.reuters.com/business/healthcare-pharmaceuticals/prices-new-us-drugs-rose-35-2023-more-than-previous-year-2024-02-23/ (Last accessed 18 Nov. 2024).
[18] *Id*.

The 2023 median annual list price for 47 new drugs entering the market in 2023 was $300,000.[19] This represents a large increase from 2021 and 2022. The median annual price was only $180,000 in 2021 and $222,000 in 2022.[20]

Generic and biosimilar drugs are less expensive than brand name drugs. The generic drug industry estimated that the U.S. healthcare system saved approximately $445 billion in 2023 and $3 trillion over the last ten years as more drugs went off patent and became generic or biosimilars.[21] The average out-of-pocket cost for a generic drug in 2023 was $7.05, while the average out-of-pocket cost for a brand name drug in 2023 was $27.10, or approximately four times more.[22]

Biosimilars (the equivalent of generics for biologics) have been a growing market, since the approval process was created nearly a decade ago. Industry estimates suggest that the substitution of biosimilars for biologics generated $12.4 billion in savings in 2023 and $36 billion since the first biosimilar entered the market in 2015.[23] In 2023, generics and biosimilars represented 90% of all prescriptions, but only 13.1% of prescription drug spending.[24]

Compared to 2023, total net spending on medicines in 2028 is expected to increase by $127 billion.[25] In the next five years, 50-55 new medicines are expected to launch per year, and medicine spending is expected to grow "between 6-9% on a list price basis and 4-7% after discounts and rebates."[26]

State:

The state is currently waiting for a segment of state data to allow for analyses of drug prices for prescription drug products across all Maryland market segments for the same year.

[19] *Id*.
[20] *Id*.
[21] Association for Accessible Medicines. *The U.S. Generic & Biosimilar Medicines Savings Report*. AAM. Sept. 2024. Available at: https://accessiblemeds.org/sites/default/files/2024-09/AAM-2024-Generic-Biosimilar-Medicines-Savings-Report.pdf (Last accessed 18 Nov. 2024).
[22] *Id*.
[23] *Id*.
[24] *Id*.
[25] IQVIA Institute. *The Use of Medicines in the U.S. 2024: Usage and Spending Trends and Outlook to 2028.* 7 May 2024. Available at: https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/the-use-of-medicines-in-the-us-2024 (Last accessed 18 Nov. 2024).
[26] *Id*.

Many of the national trends also apply to Maryland specifically. From published resources, the industry estimates suggest that the state of Maryland saved approximately $7.4 billion from generic and biosimilar medicines in 2023.[27]

2024 Key Themes and Issues Affecting Prescription Drug Affordability

There are many factors that contribute to the affordability of prescription drugs. In this section, we highlight a few themes that were notable during 2024: the continued development of Prescription Drug Affordability Boards in other states, the implementation of the Inflation Reduction Act, the continued development of biosimilar competition, and the continued expansion of glucagon-like peptide-1 receptor agonists (GLP-1RAs) as an effective therapy in managing obesity.

Prescription Drug Affordability Boards:

An increasing number of states are establishing prescription drug affordability boards: "As of April 2024, at least eleven states have enacted some form of a PDAB, and several others are considering such legislation."[28] At least four states have given their PDABs the authority to establish some form of upper payment limits that would limit the maximum price that can be paid or reimbursed for certain drugs; state law varies regarding the application of upper payment limits.[29] Many states, as well as the federal government, are working on legislation involving prescription drug affordability. The Maryland PDAB is continuing to monitor the actions of existing PDABs and the proposed legislation.

Inflation Reduction Act:

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

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[27] Association for Accessible Medicines. *The U.S. Generic & Biosimilar Medicines Savings Report*. AAM. Sept. 2024. Available at: https://accessiblemeds.org/sites/default/files/2024-09/AAM-2024-Generic-Biosimilar-Medicines-Savings-Report.pdf (Last accessed 18 Nov. 2024).
[28] Rogers, Hannah-Alise. *State Regulation of Prescription Drug Prices: Prescription Drug Affordability Boards and Related Litigation*. Congressional Research Service. 4 Sept. 2024. Available at: https://crsreports.congress.gov/product/pdf/LSB/LSB11221#:~:text=PDABs%20are%20independent%2C%20state%2Dlevel,Colorado%20case%2C%20Amgen%2C%20Inc (Last accessed 18 Nov. 2024).
[29] *Id*.

It is anticipated that the industry will respond to the price reductions, and it will be important for the Maryland PDAB to monitor these responses. For example, the industry has estimated that "Medicare Part D payers will begin to exert higher levels of formulary control in preparation for 2025 when the new cost distribution models shift upwards of $40 billion annually to payer responsibility."[30]

In 2023, 10 drugs were selected for the first cycle of Medicare price negotiations. The list prices for nearly all of these medications have been steadily climbing, with growth in list prices generally outpacing that of consumer prices overall.[31] In 2024, the negotiated prices were revealed. These negotiated prices, which will go into effect in 2026, are significantly discounted compared to 2023 list prices, with the difference between negotiated and 2023 list prices ranging from 38-79%.[32] The negotiated prices are likely to provide significant savings: estimates reveal that the negotiations would have saved a total of $6 billion to the Medicare program if the policy was in place in 2023.[33] The estimated reductions in net spending for each drug range from 42% to 0%.[34] The Department of Health & Human Services (HHS) expects that "Medicare's new authority to directly negotiate prices for certain covered drugs will improve drug affordability for people with Medicare and lower costs for the Medicare program, improving access to innovative, life-saving treatments for people that need them."[35]

[30] Greenwalt, Luke. *Top 10 U.S. Market Access Trends for 2024*. IQVIA. 15 Feb. 2024. Available at: https://www.iqvia.com/locations/united-states/blogs/2024/02/top-10-us-market-access-trends-for-2024 (Last accessed 18 Nov. 2024).
[31] ASPE (Assistant Secretary for Planning and Evaluation). *Medicare Drug Price Negotiation Program: Medicare Prices Negotiated for 2026 Compared to List and U.S. Market Prices (IRA Research Series Issue Brief)*. U.S. Department of Health and Human Services. 15 Aug. 2024. Available at: https://aspe.hhs.gov/sites/default/files/documents/3e8abec86039ac0ed674a8c5fac492e3/price-change-over-time-brief.pdf (Last accessed 18 Nov. 2024).
[32] *Id.*
[33] Hernandez, Immaculada et. al. *Interpreting The First Round Of Maximum Fair Prices Negotiated By Medicare For Drugs*. Health Affairs. 3 Sept. 2024. Available at: https://www.healthaffairs.org/content/forefront/interpreting-first-round-maximum-fair-prices-negotiated-medicare-drugs?utm_medium=social&utm_source=twitter&utm_campaign=forefront and 10.1377/forefront.20240830.863408 (Last accessed 18 Nov. 2024).
[34] *Id.*
[35] ASPE (Assistant Secretary for Planning and Evaluation). *Medicare Drug Price Negotiation Program: Medicare Prices Negotiated for 2026 Compared to List and U.S. Market Prices (IRA Research Series Issue Brief)*. U.S. Department of Health and Human Services. 15 Aug. 2024. Available at: https://aspe.hhs.gov/sites/default/files/documents/3e8abec86039ac0ed674a8c5fac492e3/price-change-over-time-brief.pdf (Last accessed 18 Nov. 2024).

Biosimilars:

The U.S. biosimilars market is continuing to grow, with the industry estimating 2023 savings from the use of biosimilars increasing 30% from 2022 to 2023 to reach $12.4 billion.[36] There is still more room for growth in biosimilar use. In 2023, biosimilars only accounted for a third of the market compared to brand biologics.[37] Many challenges to biosimilar uptake remain, including: challenges in substituting biosimilars for biologics; rebates that biologic manufacturers pay to keep the biologic on the formulary; a complex FDA approval process; variable development costs; intricate patent thickets; and perverse incentives in the supply chain. These barriers hinder the success of biosimilars and the impact they can have on making drugs more affordable. Humira was the best-selling drug in the U.S. for many years. When Humira lost its patent protection, the assumption was that biosimilars would enter the market and obtain a large market share and lower the prices. This did not happen in 2023. The collective market share of 14 biosimilar versions of Humira, made by 9 manufacturers, remained below 3% by the end of 2023.[38]

There is progress that could make biosimilars more accessible and affordable. Perhaps the biggest potential change could be updates to substitutability rules and interchangeability designations. As biosimilar manufacturers continue to face obstacles regarding biosimilar uptake, the FDA is altering its approach to classifying biosimilars under interchangeable status. Under the current regulatory framework, a biosimilar may be deemed interchangeable to a reference biologic. Under current Maryland law, pharmacists may substitute an interchangeable biosimilar for a biological product. Very few biosimilars currently have the interchangeable designation.

On June 20, 2024, the FDA issued a draft guidance for industry entitled, “Considerations in Demonstrating Interchangeability With a Reference Product: Update.”[39] This document outlined the latest considerations with respect to switching studies used to demonstrate the interchangeability of a biological product with its reference product. Due to robust national and

[36]Association for Accessible Medicines. *The U.S. Generic & Biosimilar Medicines Savings Report*. AAM. Sept. 2024. Available at: https://accessiblemeds.org/sites/default/files/2024-09/AAM-2024-Generic-Biosimilar-Medicines-Savings-Report.pdf (Last accessed 18 Nov. 2024).
[37]Association for Accessible Medicines. *The U.S. Generic & Biosimilar Medicines Savings Report*. AAM. Sept. 2024. Available at: https://accessiblemeds.org/sites/default/files/2024-09/AAM-2024-Generic-Biosimilar-Medicines-Savings-Report.pdf (Last accessed 18 Nov. 2024).
[38] Fein, Adam J. *The 2024 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*. Drug Channels Institute. Mar. 2024. Available at: https://drugchannelsinstitute.com/files/2024-PharmacyPBM-DCI-Overview.pdf (Last accessed 18 Nov. 2024).
[39] U.S. Food and Drug Administration (FDA). *Considerations in Demonstrating Interchangeability With a Reference Product: Update (Guidance for Industry - Draft Guidance)*. U.S. Department of Health and Human Services. Jun. 2024. Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-demonstrating-interchangeability-reference-product-update (Last accessed 18 Nov. 2024).

international experience demonstrating insignificant risks regarding safety or diminished efficacy when switching between a reference product and a biosimilar product, the FDA's requirements for demonstrating interchangeability would become less restrictive. Based on this new guidance, applicants submitting proposed interchangeable biosimilars for approval will be able to provide an assessment of why comparative analytical and clinical data demonstrate the same standard as a successful switching study.[40]

This evolution in the biosimilar space demonstrates increased potential for interchangeable biosimilars to gain approval and enter the market. With these and other changes in biosimilar regulation that will come in the next few years, more potential for biosimilar savings will be realized. The Maryland PDAB will continue to monitor federal and state biosimilar developments.

GLP-1 RAs:

Within the last few years, the use of GLP-1 RAs has increased significantly due to widespread utilization for diabetes and weight loss. These drugs include drugs that have been in the news and advertised lately, such as the injectables Ozempic, Jardiance, Wegovy, Mounjaro, Zepbound, Bydetta, and Bydureon.

Between 2011 and 2023, there were approximately 1 million new GLP-1 RA users in the United States, and the use of GLP-1 RAs in non-type-2-diabetes patients doubled.[41] From 2019 to 2023, these drugs were increasingly being prescribed to treat obesity, and not just diabetes. During this period, the number of patients without diabetes that started GLP-1 RA treatment in the U.S. increased more than 700%.[42] The use of GLP-1 RAs off-label has also increased, as the percentage of users taking GLP-1 RAs without FDA-approved indications almost doubled between 2019 and 2023.[43] Additionally, some GLP-1 RAs have been listed on the FDA-shortage

[40] *Id*.
[41] Pelc, Corrie. *Who uses GLP-1 drugs, and for what? Is it worsening diabetes drug shortages?* Healthline Media: Medical News Today. 25 Jul. 2024. Available at: https://www.medicalnewstoday.com/articles/glp-1-drugs-diabetes-drug-shortages (Last accessed 18 Nov. 2024).
[42] Mahase, Elisabeth. *GLP-1 agonists: US sees 700% increase over four years in number of patients without diabetes starting treatment*. The British Medical Journal (BMJ). 2024;386:11645. 23 Jul. 2024. Available at: https://www.bmj.com/content/386/bmj.q1645.full and https://doi.org/10.1136/bmj.q1645 (Last accessed 18 Nov. 2024).
[43] Pelc, Corrie. *Who uses GLP-1 drugs, and for what? Is it worsening diabetes drug shortages?* Healthline Media: Medical News Today. 25 Jul. 2024. Available at: https://www.medicalnewstoday.com/articles/glp-1-drugs-diabetes-drug-shortages (Last accessed 18 Nov. 2024).

list due to extremely high demand; these shortages allowed for a large market and distribution of less regulated, compounded versions of these drugs, sparking warnings from the FDA.[44]

Recent GLP-1 launches in the obesity market have demonstrated the value of new drugs, yet they remain surrounded by controversies regarding on-label versus off-label promotions and long-term weight loss management.[45] Furthermore, rapid uptake of these medications has caused domestic and international shortages, creating access barriers for patients which can be especially dangerous for diabetes management. The obesity drug market is forecasted to reach $100 billion by the year 2030.[46] For GLP-1 RAs specifically, the market is expected to reach $125 billion by 2033.[47]

Access to these drugs could increase dramatically depending on coverage decisions. At present, drugs used for weight loss are excluded from coverage under Medicare Part D, so GLP-1 drugs are not covered when used for weight loss (even if FDA-approved for that indication).[48] Medicare Part D allows for coverage of GLP-1 RAs that are FDA-approved for type 2 diabetes mellitus and/or cardiovascular disease (Ozempic, Mounjaro, Rybelsus, and Wegovy).[49] However, while Part D plans must cover at least two drugs for the treatment of type 2 diabetes and cardiovascular disease, they do not have to include GLP-1 RAs (and neither do enhanced alternative Part D plans).[50] Additional barriers to patient access include cost sharing, formulary restrictions, step therapy, and prior authorization.[51]

Some policymakers have tried to expand Medicare Part D coverage to include prescription drugs such as GLP-1 RAs for the treatment of obesity, but this movement is met with significant scrutiny regarding the financial impact.[52] Expanding Medicare coverage of GLP-1 RAs to treat obesity could cost several billion dollars each year, as new GLP-1 RA prescriptions for only 5%

[44] U.S. Food and Drug Administration (FDA). *FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss*. FDA. 2 Oct. 2024. Available at: https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss (Last accessed 18 Nov. 2024).
[45] Greenwalt, Luke. *Top 10 U.S. Market Access Trends for 2024*. IQVIA. 15 Feb. 2024. Available at: https://www.iqvia.com/locations/united-states/blogs/2024/02/top-10-us-market-access-trends-for-2024 (Last accessed 18 Nov. 2024).
[46] Wreschnig, Laura A. *Medicare Coverage of GLP-1 Drugs*. Congressional Research Service. 9 Sept. 2024. Available at: https://crsreports.congress.gov/product/pdf/IF/IF12758 (Last accessed 18 Nov. 2024).
[47] Manalac, Tristan. *GLP-1 Receptor Agonist Market to Reach $125B by 2033: GlobalData*. BioSpace. 20 May 2024. Available at: https://www.biospace.com/glp-1-receptor-agonist-market-to-reach-125b-by-2033-globaldata (Last accessed 18 Nov. 2024).
[48] Wreschnig, Laura A. *Medicare Coverage of GLP-1 Drugs*. Congressional Research Service. 9 Sept. 2024. Available at: https://crsreports.congress.gov/product/pdf/IF/IF12758 (Last accessed 18 Nov. 2024).
[49] *Id*.
[50] *Id*.
[51] *Id*.
[52] *Id*.

of the newly eligible Medicare recipients would increase spending by approximately $3.1 billion.[53] The next few years will show continued growth in this market, as less than 10% of the potential market of patients are currently being treated.[54]

Current Medicare law prohibits coverage of drugs used for weight loss, but Medicare Part D plans can cover GLP-1 RAs for approved indications such as type 2 diabetes and cardiovascular disease.[55] Under the Medicaid Drug Rebate Program, weight-loss drugs can be excluded from coverage. Maryland Medicaid currently provides coverage for some GLP-1 agonist medications (Ozempic, Rybelsus, and Mounjaro) to treat type 2 diabetes. In its 2024 session, the Maryland General Assembly passed a bill requiring the Maryland Department of Health, among other things, to study the impact of requiring the Maryland Medical Assistance Program to cover FDA-approved antiobesity medications.[56]

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

In 2024, the Board made significant progress implementing the Cost Review Study Process and creating the process to implement upper payment limits. The Board will continue this work in 2025.

The Board does not have recommendations for additional legislation at this time, but will continue to explore policy and legislative initiatives to make prescription drugs more affordable for Marylanders.

[53] Anderer, Samantha. *Expanded Medicare Coverage of Antiobesity Drugs May Cost Billions Each Year*. Journal of the American Medical Association (JAMA) 2024;332(14):1133. 13 Sept. 2024. Available at: https://jamanetwork.com/journals/jama/article-abstract/2823802 and doi:10.1001/jama.2024.18195 (Last accessed 18 Nov. 2024).
[54] Greenwalt, Luke. *Top 10 U.S. Market Access Trends for 2024*. IQVIA. 15 Feb. 2024. Available at: https://www.iqvia.com/locations/united-states/blogs/2024/02/top-10-us-market-access-trends-for-2024 (Last accessed 18 Nov. 2024).
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Appendix A. Board Timelines and Work on Cost Review Study Process and Upper Payment Limits

Cost Review Work and Timeline:

- Background Work/Key Decisions on Cost Review Study Process
    - Board Meeting (March 28, 2022) presentation by Hilltop Institute on methodology for calculating statutory metrics (HG 21-2c-08)
    - Board Meeting (July 25, 2022) staff presentations on overview of cost review process and implementing statutory metrics
    - Board Meeting (Sept. 26, 2022) staff presentations on identifying drugs for study (additional regulatory metrics) and process for selecting drugs for cost review
    - Board Meeting (Nov. 28, 2022) staff presentation on data sources for elements of cost review
- Proposed Regulations: COMAR 14.01.04.01-.05 Cost Review Study Process
    - Draft Regulations Posted for Public Comment - April 11, 2023 and April 24, 2023
        - Public Comments were due on May 2, 2023, and May 5, 2023, respectively.
        - 12 written comments were received
    - Revised Draft Regulations Posted for Public Comment - June 16, 2023
        - Public Comments were due on June 30, 2023.
        - 8 written comments were received
    - Revised Draft of Regulations Posted on July 17, 2024 for Board Meeting
    - Approved by Board for adoption on July 24, 2023
        - Published in the September 23, 2024 Maryland Register
        - Comments were accepted through October 23, 2024
        - 2 new written comments were received
- Final Regulations: COMAR 14.01.04.01-.05 Cost Review Study Process
    - Approved by Board as final on November 27, 2023
    - Published in the December 15, 2024 Maryland Register
    - Effective Date: December 25, 2024
- Identification of Drugs for Cost Review
    - Agenda with Potential Drugs Published on March 11, 2024
    - Board Referred Drugs to PDASC for Input at March 25, 2024 Board Meeting
    - Public Comment period began April 10, 2024 and comments were due on May 10, 2024
    - PDASC provided input at April 29, 2024 PDASC meeting
- Selection of Drugs for Cost Review
    - Drugs Selected for Cost Review at May 20, 2024 meeting
    - Approval of Therapeutic Alternatives at July 22, 2024 meeting

    - Public Comment: 60-Day public comment period on drugs selected for cost review ended on July 26, 2024
    - Request for Information: Posted on July 25, 2024 and due August 26, 2024
- Updated Regulations to Allow for Preliminary Determination (proposed amendments to COMAR 14.01.04.05 under COMAR 14.01.04 Cost Review Study Process)
    - Approved by Board as Emergency Regulations on September 10, 2024
    - Regulations posted in the November 1, 2024 Maryland Register; comments due December 2, 2024

Upper Payment Limit (UPL) Action Plan Work and Timeline:

- Board PDAB Meeting Discussion and Feedback on UPL Concept:
    - Board Meeting - May 23, 2022
        - Presentation, including UPLs
        - Received Public Comments on UPL Concept
    - Board Meeting - July 25, 2022
        - Presentation, including Summary of Public Comments
        - Vote to Move forward with UPLs
    - Board Meeting - July 24, 2023
        - Staff Presentation on UPL Action Plan
    - PDASC Meeting - August 28, 2023
        - Staff Presentation on UPL Action Plan for PDASC Input
    - Board Meeting - September 18, 2023
        - Staff Presentation on UPL Framework
    - PDASC Meeting - October 23, 2023
        - Staff Presentation on UPL Framework for Stakeholder Council Feedback
    - Supply Chain Report - January 29, 2024
        - Board Approved Supply Chain Report for Submission and Approved that it was in the best interest of the state to move forward with UPLs
    - Board Meeting - May 22, 2024
        - Board provided guidance to staff to move forward with UPL Action Plan
    - Board Meeting - July 22, 2024
        - Staff Presented Draft of Overview of UPL Action Plan for Board Input
    - PDASC Meeting - August 26, 2024
        - Staff Presented Draft Upper Payment Limit Action Plan for PDASC Input
- Framework and Background Information on UPLs included in UPL Action Plan as the first policy option
    - Draft Working Document: Supply Chain Report - Health-General § 21-2C-07 (Posted on 12/12/23; Comments were accepted through 1/10/2024)
    - Board Approved Final Draft with Approval for scrivener's errors - Supply Chain Report Approved on January 29, 2024 Board Meeting (Posted on 1/22/2024)

    - Supply Chain Report - Health-General § 21-2C-07 (Approved by the Board on 9/10/24)
- Drafts of UPL Action Plan
    - Draft Upper Payment Limit Action Plan (Posted on 8/9/2024 for Public Comment; Comments were accepted through 8/26/202)
    - Revised Draft of the Upper Payment Limit Action Plan for the 9/10/24 PDAB meeting (Posted on 8/31/24)
    - The Upper Payment Limit Action Plan - Health-General § 21-2C-13(d) (Approved by the Board on 9/10/24)
- Final UPL Action Plan
    - Approved by Legislative Policy Committee on 10/22/2024
- Draft UPL Regulations (Amendments to COMAR 14.01.01.01 (Definitions), New Regulation COMAR 14.01.01.06 (Hearing Procedures), New Chapter - COMAR 14.01.05 (Policy Review, Final Action, Upper Payment Limits))
    - Published for public comment on October 28, 2024, with comments due on November 8, 2024
    - 16 written comments received
    - Discussion on the draft regulations took place at the November 4, 2024 PDASC meeting