Boehringer Ingelheim

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Oregon Prescription Drug Affordability Board
Sent Via Email: PDAB@DCBS.Oregon.gov

Re: Oregon Prescription Drug Affordability Board's Constituent Focus Groups Surveys: Pharmaceutical Manufacturer Survey on the Use of Upper Payment Limits (UPLs)

Dear Members of the Oregon Prescription Drug Affordability Board:

On behalf of Boehringer Ingelheim Pharmaceuticals, Inc., we would like to provide feedback to the "Pharmaceutical Manufacturer Survey" issued by the Oregon Prescription Drug Affordability Board ("Board") regarding the use of upper payment limits.

Founded in 1885 and independently owned since, Boehringer Ingelheim is a research driven company with 53,000 employees around the world dedicated to the discovery and development of breakthrough therapies that transform lives, today and for generations to come. As a leading research-driven biopharmaceutical company, we create value through innovation in areas of high unmet medical need focused on breakthrough therapies and first-in-class innovations.

Boehringer understands the scrutiny over prescription drug prices. The U.S. healthcare system is complex and often does not work for patients, especially the most vulnerable. In some instances, patients face prices at the pharmacy counter that are out of reach. While we understand that there is a need to find ways to concurrently reduce state budget expenditures and reduce patient out of pocket costs, we note some important considerations with respect to the use of an upper payment limit ("UPL") and offer solutions that may address the root of the problem.

An Upper Payment Limit is Unlikely to Reduce Cost for Patients:

Applying an upper payment limit to a prescription drug for the insurer or pharmacy benefit manager ("PBM") will not directly help people at the pharmacy counter. Pharmacy counter prices are controlled by the patient's insurance plan in the form of copay or co-insurance.

Generally, pharmaceutical manufacturers provide significant discounts and rebates off the list price of their medicines to insurers, PBMs and other parties. Unfortunately, these discounts are commonly withheld from patients by these other entities. As insurers and PBMs increasingly shift the cost of care to patients, patients are faced with high out-of-pocket costs at the pharmacy counter. To help alleviate the burden of these tactics', Boehringer offers additional financial support for patients designed to support and assist patients who are unable to afford their medication because they are either uninsured or are exposed to high out-of-pocket costs due to their health plan design, i.e. the underinsured. Commercial health plans and PBMs have progressively developed various tactics — including copay

accumulators, copay maximizers, and alternative funding—that siphon patient assistance and we urge the Board to consider their direct harm to patients.

Furthermore, because of the PBM system, prescription drugs subject to an UPL will result in less favorable price concessions to PBMs which will result in PBMs shifting utilization to more expensive drugs with more favorable rebate terms to the PBM. PBMs and other middlemen seek greater rebates from manufacturers that rarely reach patients while claiming they are providing cost savings to their customers. Their goal is not to ensure the best patient outcome but to continue to extract rebates for formulary access.

An Upper Payment Limit Would Likely Hurt Patient Access and Undermine Medical Decision-Making:

Boehringer shares the Board's goal of ensuring patients have access to medicines and life-saving treatments; however, implementing an UPL may further restrict access for some patients.

Given the interconnected nature of the pharmaceutical supply chain, we are increasingly concerned that the substantial rebates and discounts provided by pharmaceutical manufacturers do not directly benefit the patient nor offset their costs at the pharmacy counter. We are concerned that the application of an UPL could exacerbate access barriers for patients – partly due to the perverse financial incentives PBMs and insurers reap – and additionally undermine the patient and physician medical decision-making process. At the sole discretion of PBMs and insurers, if they are not satisfied with rebate negotiations, they may identify another prescription drug as "preferred" and place the low-rebate (UPL-applied) drug on a less preferred tier, increasing the patient out-of-pocket costs. Additionally, the PBM and health plan may choose to remove the treatment from their formulary altogether, which could impose on the medical decisions made between physicians and their patients. A patient might be forced to forego the treatment selected by their physician, for a product deemed as "preferred" by their health plan solely due to financial incentives.

Conclusion

Boehringer recognizes the prescription drug access and cost challenges patients are burdened with, and we are committed to promoting policies that protect patients in Oregon. We encourage meaningful reforms that will help lower the price patients pay for medicines at the pharmacy, such as making monthly costs more predictable, preventing deceptive alternate funding programs (AFPs), and sharing negotiated savings on medicines with patients.

We thank you for considering feedback on the use of UPLs and consideration of our concerns. Steadfast in our commitment to our patients and access to life-saving treatments, we stand ready to be a constructive partner in this initiative.

Regards,

Bridget Walsh
VP, Government Affairs and Public Policy
Boehringer Ingelheim Pharmaceuticals, Inc.

Pharmaceutical Manufacturers

*Name of person completing survey: ***Blasine Penkowski, Chief Strategic Customer Officer***

*Name of facility/entity: Johnson & Johnson Health Care Systems Inc.

*Email: ***bpenkows@ITS.JNJ.com***

*Organization Type (Carrier, Hospital or Health System, 340B Covered Entity, Pharmacy, Pharmaceutical Manufacturer, Pharmacy Benefit Manager, Advocacy Group, Wholesaler/Distributor, Group Purchasing Organization (GPO), Pharmacy Services Administrative Organization (PSAO))

Pharmaceutical Manufacturer

When thinking about drug affordability, how much concern do you have about the impact of the cost of drugs on patients?

- Very concerned
- Somewhat concerned
- Not concerned
- Not applicable
- ***Other – J&J is concerned about both patient access to and affordability of innovative medications due to high out-of-pocket costs and burdensome benefit utilization management. However, an upper payment limit (UPL) is not the solution. J&J urges the Oregon Prescription Drug Affordability Board (the Board) to make the following policy recommendations to the Oregon Legislature:***
    1. ***Require that rebates and discounts that PBMs receive from manufacturers be directly shared with patients at the pharmacy counter;***
    2. ***Examine the use of utilization management tools and evaluating how best to regulate them in the interest of patient access and minimizing out-of-pocket (OOP) costs; and***
    3. ***Prohibit diversion of cost-sharing assistance to ensure payment made by or on behalf of patients counts towards their cost-sharing burden.***

How do you anticipate that an upper payment limit would impact your organization's revenue and budgetary considerations?

- Positive impact
- Neutral impact
- Negative impact
- Not applicable
- ***Other – A UPL is an untested, unprecedented method, the impact on revenue or budget is unknown. We also have concerns about potential legal issues surrounding UPL operationalization. Furthermore, we are greatly concerned that a UPL will negatively impact patient access and will not lower patients' OOP costs. According to a recent Avalere survey, health plans have stated that utilization management will increase.[1] We are also concerned that a UPL will have negative unintended consequences for other entities throughout the supply chain, including providers, pharmacies, and wholesalers. If providers and pharmacies do not receive adequate reimbursement that covers their administrative costs, they may suffer financial losses and choose not to offer a drug subject to a UPL. As a result, Oregon patients may not be able to access their medications.***

How do you perceive the potential effects of an upper payment limit on patient *access* to necessary medications?

[1] Partnership to Fight Chronic Disease. "Health Plans Predict: Implementing Upper Payment Limits May Alter Formularies and Benefit Design But Won't Reduce Patient Costs." Accessed June 27, 2024.

• Create opportunities for a positive impact on patient access
• Neutral impact on patient access
• ***Create challenges to patient access***

What kind of impact do you think an upper payment limit would have on a patient's *ability* to afford their medications?
• Positive impact
• Neutral impact
• ***Negative impact***

What challenges might your organization face in adjusting to the constraints imposed by an upper payment limit (select all that apply)?
• Increased administrative burden
• Supply chain disruptions due to shortages or inability to sell into a market
• ***Compliance with regulatory requirements***
• ***Other (please specify) – A UPL is an untested, unprecedented method, with no existing system for implementation. In addition, UPLs will be in conflict with existing contracts across the entire supply chain. We also have concerns about potential legal issues surrounding UPL operationalization. Furthermore, we are greatly concerned that a UPL will negatively impact patient access and will not lower patients' OOP costs. According to a recent Avalere survey, health plans have stated that utilization management will increase.[1] We are also concerned that a UPL will have negative unintended consequences, including administrative burden, for other entities throughout the supply chain, including providers, pharmacies, and wholesalers. If providers and pharmacies do not receive adequate reimbursement that covers their administrative costs, they may suffer financial losses and choose not to offer a drug subject to a UPL. As a result, Oregon patients may not be able to access their medications.***

What challenges do you foresee for your company if an upper payment limit is implemented? (Select all that apply)
• Reduced revenue
• Limited R&D funding
• ***Compliance concerns***
• Competitive disadvantages
• ***Other (please specify) – A UPL is an untested, unprecedented method, and the impact on revenue or budget is unknown. We also have concerns about potential legal issues surrounding UPL operationalization. Furthermore, we are greatly concerned that a UPL will negatively impact patient access and will not lower patients' OOP costs. According to a recent Avalere survey, health plans have stated that utilization management will increase.[1] We are also concerned that a UPL will have negative unintended consequences for other entities throughout the supply chain, including providers, pharmacies, and wholesalers. If providers and pharmacies do not receive adequate reimbursement that covers their administrative costs, they may suffer financial losses and choose not to offer a drug subject to a UPL. As a result, Oregon patients may not be able to access their medications.***

The Oregon PDAB Is also interested in hearing about alternative policy approaches and recommendations that you may have. The following questions will provide you with an opportunity to provide more detailed information on approaches, recommendations, or concerns.

How could upper payment limits create meaningful cost savings for all consumers and purchasers?

• ***UPLs are unlikely to create any cost savings for consumers or purchasers. Patient OOP cost is set by health plans as a part of insurance benefit design, and health plans often base patients' coinsurance on the list***

price of a drug rather than the discounted net price plans receive.[2] A recent Avalere survey commissioned by the Partnership to Fight Chronic Disease further supports this assertion. In the survey, health plans stated "Payers will not pass their savings (if any) onto individuals. It's not realistic and somebody will need to make up the differences."[1] Interviewed plans also stated that they were unlikely to lower plan deductibles or maximum out-of-pocket limits as a result of a UPL.[1]

How would your organization utilize savings resulting from an upper payment limit (if applicable)?
• ***Not applicable.***

What could be potential administrative burdens or operational challenges associated with implementing an upper payment limit?
• ***There is no current system for operationalizing UPLs. We have concerns about potential legal issues surrounding UPL operationalization. Moreover, as UPLs ignore the interconnected market realities of the drug pricing ecosystem and supply chain, these price-setting thresholds may have unintended consequences across payer and PBM formularies, price-reporting metrics, provider reimbursement and patient plan and benefit options.[3]***

Moreover, UPLs are unlikely to create any cost savings for consumers or purchasers. Patient OOP cost is set by health plans as a part of insurance benefit design, and health plans often base patients' coinsurance on the list price of a drug rather than the discounted net price they receive.[2] A recent Avalere survey commissioned by the Partnership to Fight Chronic Disease further supports this assertion. In the survey, health plans stated "Payers will not pass their savings (if any) onto individuals. It's not realistic and somebody will need to make up the differences."[1] Interviewed plans also stated that they were unlikely to lower plan deductibles or maximum out-of-pocket limits as a result of a UPL.[1]

What recommendations, if any, do you have regarding the potential administrative burdens or operational challenges associated with implementing an upper payment limit?
• ***We recommend not implementing a UPL, and instead, we urge the Board to make the following policy recommendations to the Oregon Legislature:***

1. ***Require that rebates and discounts that PBMs receive from manufacturers be directly shared with patients at the pharmacy counter;***
2. ***Examine the use of utilization management tools and evaluating how best to regulate them in the interest of patient access and minimizing OOP costs; and***
3. ***Prohibit diversion of cost-sharing assistance to ensure payment made by or on behalf of patients counts towards their cost-sharing burden.***

Are there alternative policy approaches that you believe would be more effective in addressing drug affordability while preserving innovation and investment in research and development?
• ***Yes, we urge the Board to make the following policy recommendations to the Oregon Legislature:***

1. ***Require that rebates and discounts that PBMs receive from manufacturers be directly shared with patients at the pharmacy counter;***
2. ***Examine the use of utilization management tools and evaluating how best to regulate them in the interest of patient access and minimizing OOP costs; and***
3. ***Prohibit diversion of cost-sharing assistance to ensure payment made by or on behalf of patients counts towards their cost-sharing burden.***

How can policymakers ensure that an upper payment limit policy is implemented in a manner that promotes transparency, fairness, and affordability for both payers and patients?

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[2] PhRMA. "Commercially-Insured Patients Pay Undiscounted List Prices for One in Five Brand Prescriptions, Accounting for Half of Out-of-Pocket Spending on Brand Medicines." Accessed June 27, 2024.
[3] Janssen. "Influence of Prescription Drug Affordability Board and Upper Payment Limits on the State Drug Pricing Ecosystem." Accessed June 27, 2024.

• Given the complexity of the healthcare ecosystem, a UPL cannot be implemented in a manner that promotes transparency, fairness, or affordability for payers and patients. A UPL is an untested, unprecedented method, and the impacts on revenue or budget are unknown. We also have concerns about potential legal issues surrounding UPL operationalization. Furthermore, we are greatly concerned that a UPL will negatively impact patient access and will not lower patients' OOP costs. According to a recent Avalere survey, health plans have stated that utilization management will increase.[1] We are also concerned that a UPL will have negative unintended consequences for other entities throughout the supply chain, including providers, pharmacies, and wholesalers. If providers and pharmacies do not receive adequate reimbursement that covers their administrative costs, they may suffer financial losses and choose not to offer a drug subject to a UPL. As a result, Oregon patients may not be able to access their medications.

What specific factors or considerations should policymakers take into account when setting an upper payment limit for prescription drugs?

• A UPL is an untested, unprecedented method, and the impact on revenue or budget is unknown. We also have concerns about potential legal issues surrounding UPL operationalization. Furthermore, we are greatly concerned that a UPL will negatively impact patient access and will not lower patients' OOP costs. According to a recent Avalere survey, health plans have stated that utilization management will increase.[1] We are also concerned that a UPL will have negative unintended consequences for other entities throughout the supply chain, including providers, pharmacies, and wholesalers. If providers and pharmacies do not receive adequate reimbursement that covers their administrative costs, they may suffer financial losses and choose not to offer a drug subject to a UPL. As a result, Oregon patients may not be able to access their medications.

To avoid unnecessary spending of taxpayers' dollars, we urge the Board to make the following policy recommendations to the Oregon Legislature:

1. ***Require that rebates and discounts that PBMs receive from manufacturers be directly shared with patients at the pharmacy counter;***
2. ***Exam the use of utilization management tools and evaluating how best to regulate them in the interest of patient access and minimizing OOP costs; and***
3. ***Prohibit diversion of cost-sharing assistance to ensure payment made by or on behalf of patients counts towards their cost-sharing burden.***

June 28, 2024

VIA ELECTRONIC FILING

Oregon Prescription Drug Affordability Board
350 Winter Street NE
Salem, Oregon 97309-0405
pdab@dcbs.oregon.gov

Dear Members of the Oregon Prescription Drug Affordability Board:

GSK and ViiV Healthcare (ViiV) appreciate the opportunity to jointly submit a comprehensive response to the Oregon Prescription Drug Affordability Board's (Board) survey, as part of the development of a plan to establish upper payment limits (UPLs) required by Senate Bill 192.

GSK is a science-led global healthcare company with a special purpose to unite science, technology, and talent to get ahead of disease together. We focus on science of the immune system, human genetics, and advanced technologies to impact health at scale. We prevent and treat disease with vaccines, as well as specialty, and general medicines.

ViiV is the only independent, global specialist company devoted exclusively to delivering advancements in human immunodeficiency virus (HIV) treatment and prevention to support the needs of people with HIV and those vulnerable to HIV. From its inception in 2009, ViiV has had a singular focus to improve the health and quality of life of people affected by this disease and has worked to address significant gaps and unmet needs in HIV care.

We reviewed the survey questions that were sent out to manufacturers and appreciated the interest in hearing stakeholder perspective on this important issue. However, we felt that many of questions did not leave room to expand on the nuances of UPL proposals. Therefore, we have elected to jointly submit this letter that explains the impact that UPLs will have on patients and access to medications.

Patient accessibility to medication has always been, and remains, a top priority for both GSK and ViiV. While there are many solutions that could have a positive impact on patient affordability and accessibility, establishing UPLs is not one of them.

GSK and ViiV are concerned that added complexity and lack of transparency on UPLs could drive supply chain costs higher over time and exacerbate patient access concerns. Numerous operational challenges associated with implementing UPLs exist, which are likely to create financial and logistical burdens for all stakeholders involved in the drug supply chain, including pharmacies, wholesalers, providers, payers, and patients.

For example, effectuating a UPL price through the supply chain could necessitate new pharmacy and wholesaler acquisition/tracking systems and the introduction of payment streams that do not exist today. Further, any challenges in pharmacy and wholesaler supply operations can directly lead to gaps in patient access, particularly if a patient's local pharmacy is unable to operationalize and comply with the UPL-driven requirements.

Also critical for patients, payers have indicated that drugs subject to UPLs or other drugs in their therapeutic class could have more utilization management (e.g., prior authorization) once a UPL is implemented, as well as cause changes in formulary tiering, which could increase patients' out of pocket costs.[1] UPLs are also likely to have long-term effects on the prescription drug ecosystem, including provider access, copay assistance needs, and manufacturer research and development (R&D).

Equally concerning, affordability reviews that inform upper limit decisions target the most innovative medicines, disproportionately impacting patients with diseases where there is high unmet need and where low-cost treatment options are often not available.

GSK and ViiV support policy solutions that transform our healthcare system into one that improves patient outcomes, achieves higher value care and rewards innovation. Policies that can positively impact patients include:

- Requiring pharmacy benefit managers (PBMs) to pass manufacturer rebates to patients at the pharmacy counter;
- Requiring PBMs to be paid a flat fee based on the value of the services they provide, rather than a percentage of a drug's list price; and
- Closing policy loopholes in health insurer coverage that allow copay accumulator adjustment programs, copay maximizer programs, and alternative funding programs to interfere with patient cost savings.

In summary, medications prescribed should be based on the best clinical outcomes as decided by providers and patients and not strictly by cost considerations. Imposing arbitrary UPLs guided by misinformed affordability reviews may limit access to life-saving medicines and vaccines and indirectly harm patients' health. GSK and ViiV urge the Board to consider these unintended consequences as it seeks to implement Senate Bill 192 and how its plan to establish an UPL may impact access to vital medications and vaccines for Oregonians.

Thank you again for the opportunity to engage with the Board and your survey efforts. We welcome a continued dialogue on this issue and look forward to future engagement with you on solutions that maintain and increase access to vital medications in Oregon. Please feel free to contact Christian Omar Cruz at Christian.O.Cruz@gsk.com with any questions.

Sincerely,

Harmeet Dhillon
Head, Public Policy
GSK

Carie Harter
Senior Director, Government Relations
ViiV Healthcare

[1] Avalere. April 2024. "Research Explores Health Plan Perceptions of PDABs and UPLs." Accessed at https://avalere.com/insights/research-explores-health-plan-perceptions-of-pdabs-and-upls.

PhRMA
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June 28, 2024

Oregon Prescription Drug Affordability Board
350 Winter Street NE
Salem, OR 97309-0405
pdab@dcbs.oregon.gov

Re: Oregon Prescription Drug Affordability Board: Pharmaceutical Manufacturer Survey Dated June 14, 2024

Dear Members of the Oregon Prescription Drug Affordability Board:

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is writing in response to the Oregon Prescription Drug Affordability Board's (the "PDAB" or "Board") Pharmaceutical Manufacturer Survey distributed June 14, 2024 ("Manufacturer Survey").[1] PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. PhRMA is concerned that any proposed Upper Payment Limit ("UPL") scheme would arbitrarily cap pharmaceutical prices, fail to recognize the complexity of the pharmaceutical supply chain, and would overlook meaningful policy alternatives that would substantially reduce the cost of medicines for Oregonians. A proposed UPL scheme would also raise concerns under the Supremacy Clause of the U.S. Constitution, among other constitutional concerns.[2]

PhRMA continues to have significant concerns about the impact that UPLs would have on Oregonians. UPLs could restrict patient access to medicines and result in fewer new treatments for patients, and ultimately do not carry any guarantee of savings being passed on to patients. Further, the UPL process raises fundamental administrative and operational questions and concerns and creates risks of arbitrary decision-making by the Board. PhRMA cautions the state against considering moving forward with any UPL plan given the risks and legal questions associated with such price controls. Below, PhRMA provides more details about its concerns in its responses to the questions posed in the Board's Manufacturer Survey.[3]

I. How could upper payment limits create meaningful cost savings for all consumers and purchasers?

PhRMA is concerned that UPLs would not translate into meaningful cost savings for patients. UPLs focus on limiting the prices set by the biopharmaceutical industry and ignore the function of other stakeholders in determining what patients ultimately pay for medicines, including insurers, pharmacy benefit managers ("PBMs"), wholesalers, and the government. The important role that these entities play in determining drug coverage and patient out-of-pocket costs seems to be overlooked by the proposed UPL scheme. For example, PBMs and payers – which dictate the terms of coverage for medicines and the amount a patient ultimately pays – negotiate substantial rebates and discounts from manufacturers. If payers, PBMs, distributors, and other direct purchasers are not required to pass UPL-related discounts onto patients, it would ignore the role that these entities play in issues of consumer (i.e., patient) affordability.

[1] Manufacturer Survey (June 4, 2024), *available at* https://mslc.qualtrics.com/jfe/form/SV_39ijG1FM8LzFDMy.
[2] *See, e.g.*, *BIO v. District of Columbia*, 496 F.3d 1362 (2007); Amgen v. Colo. Prescr. Drug Affordability Rev. Bd., No. 1:24-cv-00810 (D. Colo. filed Mar. 22, 2024).
[3] In filing this comment letter, PhRMA reserves all rights to legal arguments with respect to Oregon Senate Bill 844 (2021), as amended by Oregon Senate Bill 192 (2023) (collectively, the "PDAB Statute").

Pharmaceutical manufacturers pay substantial rebates and discounts – approximately $267 billion in 2023 alone.[4] By focusing exclusively on the amounts paid by the direct purchaser (e.g., often the PBM or payer), UPL price controls do not ensure that existing rebates and discounts make their way to offsetting patient costs at the pharmacy counter.[5] This has real consequences for patients. According to research from the Berkeley Research Group ("BRG"), rebates, discounts, and fees account for an increasing share of spending for brand medicines each year, while the share received by manufacturers has decreased over time. In 2021, net prices for brand medicines were, on average, 53% lower than the list prices due to significant rebates, discounts, and other payments from manufacturers.[6] Simultaneously, the growth rate of prescription drug costs has slowed in recent years, with average net prices for brand medicines grew by 3.0% in 2023, below the rate of inflation for the fifth year in a row. Looking ahead, average net price growth is projected to be -1 to -4% per year through 2028.[7] Increased rebates and discounts have largely offset these modest increases in list prices and reflect the competitive market for brand medicines, yet UPLs would not require that these existing rebates and discounts are actually carried forward by plans and PBMs to patients to make their medicines more affordable.

II. What could be potential administrative burdens or operational challenges associated with implementing an upper payment limit?

Establishing UPLs would carry significant administrative and operational burdens and concerns. UPLs restrict patients' access to medicines and result in fewer new treatments. In a recent study of health plan payers interviewed by Avalere about the impacts of a potential UPL, most payer interviewees indicated that "if a drug were to become subject to a UPL, then providers may experience challenges acquiring the product. Interviewees elaborated that provider reimbursement based on a selected drug's UPL may not be adequate relative to their acquisition costs."[8] The same study found that payers did not expect UPLs to lower patient out-of-pocket costs: "Most payers (five of six) did not anticipate that UPL-related savings would be passed on to patients in the form of lower premiums, deductibles, or cost sharing." This study highlights some the supply chain concerns and the potential impacts of UPLs on patients access to prescription drugs.

This concern is further demonstrated by the experience of states that have enacted UPL authority; four states have enacted laws that would allow them to set a UPL for certain medicines, but no state has implemented a UPL to date. Existing state UPL proposals drastically over simiplify the complexity of the pharmaceutical payment and reimbursement system and have created operational concerns across a variety of supply chain entities. For example, the Maryland Department of Public Health expressed concerns to the state legislature that a UPL could put federal matching dollars at risk for the state's Medicaid program and inadvertently cost the state more money than it might save.[9] Maryland's board has been meeting regularly since 2020, but has just begun the process of affordability reviews.[10] In November 2022, adoption of Colorado's rulemaking on the UPL was delayed to address concerns raised by stakeholders and give the board more time to work on the rule; the Colorado Hospital Association had notably raised concerns about the unintended consequences the

[4] IQVIA. "Use of Medicines in the U.S. 2024: Spending and Usage Trends and Outlook to 2028." April 2024.
[5] *See* A. Fein, *The 2020 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*, Drug Channels Institute (Mar. 2020).
[6] IQVIA. "Use of Medicines in the U.S. 2024: Usage and Spending Trends and Outlook to 2028." Published April 2024.
[7] *Id.*
[8] Research Explores Health Plan Perceptions of PDABs and UPLs. April 2, 2024. Accessed at https://avalere.com/insights/research-explores-health-plan-perceptions-of-pdabs-and-upls.
[9] Letter to House Health and Government Operations Committee from Maryland Department of Health re: HB 279, February 2, 2023. https://mgaleg.maryland.gov/cmte_testimony/2023/hgo/1OoeMJLHVifacq1rfNcQYND5k-v0L8ThH.pdf.
[10] *See* Maryland PDAB, "Board Selected Drugs and any applicable information," https://pdab.maryland.gov/Pages/board-selected-da-info.aspx (subsection of page on "Timeline Information for Cost Review").

UPL would have on hospital revenue and on their ability to bulk purchase drugs which further highlights concerns throughout the supply chain on the adoption of a UPL.[11]

Since Oregon's Prescription Drug Affordability Board began operation in 2022, PhRMA has raised signification administrative and operational concerns about the process and work of the Board.[12] The Board itself recognizes that there are issues that need to be addressed, as shown by its decision to on June 26, 2024 to postpone further affordability reviews until 2025 while it reviews and improves its affordability review criteria and methods. These issues and concerns would be exacerbated by the addition of a UPL scheme, which would significantly expand the potential consequences of the Board's work. We reiterate the following non-exhaustive list of challenges and concerns that we have previously raised with the Oregon PDAB and similar Boards in other states:

- **Lack of Clear, Specific, and Meaningful Standards**. Across states that have implemented affordability review or UPL regulations to date, the rules for evaluating affordability and establishing UPLs have consistently suffered from an overriding lack of clear, specific, and meaningful standards.[13] These rules incorporate extensive lists and categories of information and data sources that must (or may) consider as part of the multi-step affordability review and UPL-setting process, but have been devoid of specific rules that explain *how* the implementing agencies would utilize such information in a consistent and balanced way to make informed assessments about questions of affordability and the need for a UPL. PhRMA is concerned that any UPL-setting process in Oregon would similarly lack clear and concrete standards to guide the Board's discretion in establishing a UPL.

  Further, the vagueness of the standards adopted to date raises concerns regarding whether it would be lawful to impose UPLs based on such standardless evaluations. Notably, under the Oregon Administrative Procedures Act ("APA"), agencies are required to render decisions in a manner that is "rational, principled, and fair, rather than ad hoc and arbitrary."[14] As such, courts have long held that agencies like the Board must "make policies for even application" across regulated entities and products," which is directly contrary to affordability review and UPL rules that authorize evaluations based on undefined and unascertainable standards.[15]

- **Data Quality Concerns**. PhRMA also questions whether the Board would provide adequate processes and safeguards to verify the reliability of data used to support a potential UPL. The UPL-setting process, similar to the Board's affordability reviews, would be dependent on the fidelity of the information being relied upon in the Board's decision-making. Information bearing on the criteria for evaluating affordability or setting a UPL is likely to be drawn from a variety of sources, including reports from insurers, manufacturer data, and various other third-party sources. Certain sources of information may be unreliable or offer only a selective portion of the full picture relevant to the Board's selection of drugs for affordability review. Oregon's affordability review process to date has been rife with persistent errors, causing the board to

[11] Colorado PDAB, Draft Meeting Minutes, Friday November 18, 2022, https://drive.google.com/file/d/1qHM7PkGBGlXzVmq_T-kkQU85EEWUdt8f/view; Colorado Hospital Association, letter to CO PDAB, October 6, 2022, "Re: CHA Comments on Oct. 7 rulemaking hearing regarding the Proposed Draft Rule Part 4 – Upper Payment Limit Methodology."

[12] PhRMA has filed 27 comment letters to date with the Oregon PDAB, detailing, among other things, our ongoing concerns with the Board's affordability review process and procedures. *See, e.g.*, Letter from PhRMA to Board (May 12, 2024); Letter from PhRMA to Board (Feb. 17, 2024); Letter from PhRMA to Board (Oct. 15, 2023).

[13] *See, e.g.,* Letter from PhRMA to Board (June 23, 2023); Letter from PhRMA to Washington PDAB (Apr. 11, 2024); Letter from PhRMA to Maryland PDAB (June 30, 2023); Letters from PhRMA to Colorado PDAB (Nov. 14, 2022) (regarding draft affordability review and UPL regulations).

[14] *Gordon v. Bd. of Parole & Post Prison Supervision*, 343 Or. 618, 633 (2007).

[15] *Sun Ray Drive-In Dairy, Inc. v. Oregon Liquor Control Comm'n*, 16 Or. App. 63, 72 (1973).

alter the number of drugs eligible for affordability review on multiple occasions, even after the list was finalized and the work of reviewing drugs had begun.[16]

- **Confidentiality Concerns**. UPL-setting is also likely raise substantial confidentiality concerns. PhRMA has consistently stressed in our comments that, under the Board's existing authority, it has not adequately addressed how it will maintain confidentiality of the materials it receives as part of its affordability reviews.[17] State and federal law protect manufacturers' confidential, trade secret, and proprietary information from disclosure; such information cannot be publicly disclosed without violating state and federal prohibitions against the misappropriation of trade secrets. Further, the Fifth Amendment's prohibition against taking private property without just compensation prohibits the uncompensated disclosure of trade secrets, and courts have made clear that "when disclosure [of pricing information] is compelled by the government," even the "failure to provide adequate protection to assure its confidentiality ... can amount to an unconstitutional 'taking' of property."[18] The U.S. District Court for the District of Oregon recently ruled that the "public disclosure" of manufacturers' trade secrets violates the Fifth Amendment "[u]nless just compensation is provided" at the time of disclosure.[19] These concerns would be heightened if the Board were also given authority to establish UPLs, particularly if as part of the UPL process, the Board sought to obtain sensitive financial or commercial information from stakeholders.

III. Are there alternative policy approaches that you believe would be more effective in addressing drug affordability while preserving innovation and investment in research and development?

Implementing price controls diminishes the incentives for biopharmaceutical manufacturers to invest in and introduce new medicines and could limit the prescription drug options available to Oregon residents. Research shows that "[i]t is simply not true that government can impose significant price controls without damaging the chances for future cures."[20] Experts estimate a 50% decrease in the price of medicines would result in a 25% to 60% decrease in the number of new drugs in the pipeline.[21] U.S. patients enjoy earlier and less restrictive access to new therapies,[22] a finding that is reinforced by HHS's own analysis of Medicare Part B drugs which showed that only 11 of the 27 drugs examined (41%) were available in all 16 comparator countries, nearly all of which have single-payer healthcare systems.[23] In countries where governments set medicine prices, patients have access to fewer treatment options. For example, the U.S. has access to nearly 85% of all medicines launched between 2012 and 2021, while just 61% are available in Germany, 59% in the

[16] See, for example, the issues highlighted in PhRMA's comments regarding the Board's May 2024 and November 2023 meetings and meeting materials. Letter from PhRMA to Board (May 12, 2024); Letter from PhRMA to Board (Nov. 11, 2023).
[17] Letter from PhRMA to Board (May 14, 2023), 5; Letter from PhRMA to Board (Apr. 16, 2023), 8; Letter from PhRMA to Board (June 20, 2022), 3-4.
[18] *St. Michael's Convalescent Hosp. v. State of Cal.*, 643 F.2d 1369, 1374 (9th Cir. 1981).
[19] *PhRMA v. Stolfi*, --- F. Supp. 3d ----, 2024 WL 1177999 (D. Ore. Mar. 19, 2024), *appeal pending*, No. 24-1570 (9th Cir. filed Mar. 15, 2024).
[20] Kennedy, J. The Link Between Drug Prices and Research on the Next Generation of Cures. Information Technology & Innovation Foundation. Sept. 9, 2019. Available at https://itif.org/publications/2019/09/09/link-between-drug-prices-and-research-next-generation-cures.
[21] Abbot, T. and Vernon, J. The Cost of US Pharmaceutical Price Reductions: A Financial Simulation Model of R&D Decisions. National Bureau of Economic Research. Available at https://www.nber.org/papers/w11114; Civan, A. & Maloney, M. (2009). The Effect of Price on Pharmaceutical R&D. The B.E. Journal of Economic Analysis & Policy, 9(1).
[22] IQVIA Institute, Global Oncology Trends 2017, Advances, Complexity and Cost. May 2017.
[23] U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation (ASPE). Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures. October 25, 2018.

U.K., 51% in Japan, 52% in France, 45% in Canada, and 34% in Australia.[24]

There are a range of policy alternatives to UPLs that more directly and effectively address issues of affordability and access, while also better preserving incentives for innovation and investment in research and development of new and potentially transformative medicines. PhRMA would like to highlight some proposed policies that we believe can help patients better afford their medications, without putting access to care at risk.

Biopharmaceutical manufacturers provide significant discounts, rebates, and other price concessions to PBMs and health carriers, but many patients don't benefit directly from these discounts. On average, pharmaceutical companies rebate approximately 53% of a medicine's list price back to insurance companies and middlemen like PBMs.[25] While health insurers claim that at least a portion of these discounts are used to reduce premiums, research shows that sharing these rebates and discounts directly with patients at the pharmacy counter would have little impact on premiums and significantly benefit consumers.[26] Studies predict that requiring health insurers and PBMs to share negotiated discounts and rebates at the pharmacy counter could save some patients $900 annually in out-of-pocket expenses without significantly increasing their premiums.[27] A study of recently enacted legislation in Arkansas requiring health insurance companies and PBMs to share rebates with patients found no evidence that the policy has caused premium increases.[28] Patients should benefit directly from negotiated rebates and discounts, and health insurers and PBMs should no longer be able to retain those price concessions.

In addition to rebates, PBMs have recently been increasingly profiting off fees and other compensation that are tied to the list price of a medicine, which has created perverse incentives in the marketplace. The largest PBMs wield significant sway over the marketplace, both by virtue of their market share and their relationships with other market participants including health plans, pharmacies, and other providers.[29] The combined market share of the three largest PBMs has grown significantly, from 48% in 2010 to 80% in 2021,[30] and just six companies control 96% of the PBM market.[31] Concern about the influence of PBMs on the supply chain have been raised by Oregon,[32] Congress, and the Federal Trade Commission.[33] When investigating PBMs, the U.S. Senate Finance Committee concluded that, "PBMs have an incentive for manufacturers to keep list prices high, since the rebates, discounts, and fees PBMs negotiate are based on a percentage of a drug's list price – and PBMs may retain at least a portion of what they negotiate."[34] Oregon's Secretary of State performed an

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[24] PhRMA analysis of IQVIA Analytics Link and U.S. Food and Drug Administration, European Medicines Agency, Japan Pharmaceuticals and Medical Devices Administration, Health Canada and Australia Therapeutic Goods Administration data. Note: Sample includes new active substances launched globally from January 1, 2012 to December 31, 2021. Updated June 2022.
[25] IQVIA. "Use of Medicines in the U.S. 2024: Spending and Usage Trends and Outlook to 2028." April 2024.
[26] PCMA, https://www.pcmanet.org/rx-research-corner/the-path-of-a-rebate-from-drug-companies-through-pharmacy-benefit-companies-to-the-employer-and-all-the-way-to-patients/12/04/2023/. Dec 4, 2023
[27] Milliman. "Measuring the Impact of Point of Sale Rebates on the Commercial Health Insurance Market." July 2021. https://www.milliman.com/-/media/milliman/pdfs/2021-articles/7-6-21-measuring-the-impact-of-point-of-sale-rebates.ashx.
[28] Milliman. "Premium Impacts of POS Rebate Implementation in the ACA Market in the State of Arkansas" January 2024.
[29] https://www.drugchannels.net/2021/04/the-top-pharmacy-benefit-managers-pbms.html.
[30] Fein AJ. "The Top Pharmacy Benefit Managers of 2021: The Big Get Even Bigger." Drug Channels. April 5, 2022.
31 Sweeney E. "Lawmakers ask FTC for retrospective review of PBM mergers," Fierce Healthcare. July 2018.
[32] Oregon Health Authority, "Pharmacy Benefit Managers: Poor Accountability and Transparency Harm Medicaid Patients and Independent Pharmacies," August 2023.. The Oregon Legislature has considered dozens of bills in the past few years to regulate and rein in the abusive practices of the PBMs. *See* "Drug supply companies squeezing pharmacies out of existence, Oregon lawmakers warn." January 26, 2023.; "Oregon set to tighten rules for pharmacy benefit managers. Here's what they do." March 10, 2024.
[33] Federal Trade Commission. "FTC Launches Inquiry into Prescription Drug Middlemen Industry." Press Release, June 7, 2022; Federal Trade Commission. "FTC Deepens Inquiry into Prescription Drug Middlemen." Press Release, May 17, 2023.
[34] Senate Finance Committee. "Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug," 2021.

audit of PBM practices in the state, finding that "there is growing public interest in assessing the role, value of, and significant power and influence held by third-party organizations known as pharmacy benefit managers."[35]

These abusive practices of PBMs not only raise pharmacy costs for patients, but they also contribute to higher overall costs in the health care system. A study by the Washington State Pharmacy Association and 3-Axis Advisors analyzed millions of pharmacy claims and found that PBMs are driving up costs by charging employers more than necessary to participate in plans, retaining increasingly more than pharmacies are reimbursed (a practice known as "spread pricing"), and steering plans and patients to their affiliated mail-order pharmacies, allowing them to retain more profit from each transaction.[36] A study of Oregon pharmacy claims found in one example, PBMs were marking up a generic drug by as much as 800%, and profiting approximately $1.9 million on the spread pricing of just one drug.[37]

Instead of untested proposals, patients need concrete reforms that will help lower the price they pay for medicines at the pharmacy. PhRMA urges the Board to consider common-sense policies to address the lack of oversight of out-of-pocket pharmacy costs set by health insurers and middlemen. State policymakers can:

- Require middlemen to share the savings – rebates, discounts, and other price concessions they receive from manufacturers – directly with patients at the pharmacy counter;
- Make manufacturer coupons count toward deductibles and other out-of-pocket requirements so that patients get the full benefit of programs meant to help them access their medicines;
- Help patients from day one by requiring all plans to cover certain medications used to treat chronic conditions with no deductible; and
- Tying the fees pharmaceutical supply chain middlemen charge to the services they provide, not the list price of a medicine.

* * *

On behalf of PhRMA and our member companies, thank you for consideration of our comments. Although PhRMA has concerns about the potential addition of UPL authority in Oregon, we stand ready to be a constructive partner in this dialogue. Please contact dmcgrew@phrma.org with any questions.

Sincerely,

Dharia McGrew, PhD
Director, State Policy

Merlin Brittenham
Assistant General Counsel, Law

[35] Oregon Health Authority, "Pharmacy Benefit Managers: Poor Accountability and Transparency Harm Medicaid Patients and Independent Pharmacies," August 2023..
[36] Three Axis Advisors, "Understanding Drug Pricing from Divergent Perspectives State of Washington Prescription Drug Pricing Analysis", June 2024. https://cdn.ymaws.com/www.wsparx.org/resource/resmgr/pbm/3aa_washington_report_202406.pdf
[37] Three Axis Advisors, "Understanding Pharmacy Reimbursement Trends in Oregon: The High Costs of Low Prices", October 2022. https://oregonpharmacy.org/wp-content/uploads/2022/10/Oregon_Report_20221027-FINAL.pdf

House Committee on Education and The Workforce
"Competition and Transparency: The Pathway Forward For A Stronger Health Care Market"
June 21, 2023

Written Testimony of Greg Baker, BS Pharm
CEO of AffirmedRx

Chairman Good, Ranking Member DeSaulnier, and distinguished members of the House Subcommittee, I would like to thank you for the invitation to speak with you on the necessity of increasing competition and transparency in health care.

My name is Greg Baker. I, first and foremost, am a pharmacist. I am also the CEO of AffirmedRx which is a transparent PBM I founded, headquartered in Louisville, KY. I have spent the past 30 years working in different areas of pharmacy with the past 11 years dedicated to collaborating directly with jumbo self-funded employers to help define and develop their pharmacy programs. Our goal at AffirmedRx is to partner with employers to deliver patient-centric pharmacy benefits with a mission to improve health care outcomes by bringing clarity, integrity and trust to pharmacy benefit management.

With my expertise in pharmacy benefits, I will focus my comments on competition and transparency within this industry. While there are around 70 PBMs currently doing business in the United States, only three large PBMs control up to 80% of the market in the USA. These PBMs are not constrained by any obligation to be transparent on their pricing and what they pay their own pharmacy versus what they pay other community pharmacies. They are not transparent in what their corporately owned and newly conceived group purchasing organizations (GPOs) receive in total manufacturer revenue versus what they pay back out to employers to help drive down the total cost of care.

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They do not share global claims data or per claim level rebate amounts. They are not transparent on why they prefer branded medications over lower-cost generic medications which, for the 55% of self-funded patients with high deductible or co-insurance plans, increases their out-of-pocket costs at the pharmacy counter.

Additionally, over the past 5 years, through mergers and acquisitions, these PBMs have become part of large, vertically integrated systems. We have been told for years how this vertical integration will improve outcomes and lower the cost of health care. It is our view that instead of helping they have used their significant market position and profit-focused business practices to secure outsized margins for the services they provide. This has led to higher costs, lower medication adherence, lower condition control and has increased morbidity and mortality of U.S. citizens.

Let us consider these facts on the state of the pharmaceutical industry today:

- Medications can be a key component to reduce health risk, control chronic disease and treat illnesses. In the U.S., illness and death from non-optimized medication therapy cost $528.4 billion annually – equivalent to 16% of total U.S. healthcare expenditures.
- Patients starting new prescriptions as prescribed by their physicians abandoned 94 million prescriptions at pharmacies in 2022 with increasing frequency as costs rise.
- A JAMA article published in June 2021 suggest that while drug manufacturers may increase list prices in order to offer larger rebates to insurers, such increases were associated with increased out-of-pocket costs to patients:
    - This study found that between 2014-2018 list prices from manufacturers grew 13.3% while rebates paid to PBMs increased 24.4%.
    - With the manufacturers raising list prices they also found that every $1 increase in list price equated to an increase of $2.09 in patient out-of-pocket costs. While we have had much debate over the list

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price increases by pharmaceutical manufacturers, these numbers clearly show how PBMs are retaining the most value and the American public continues to suffer greater drug affordability issues.
- Finally, the report sadly pointed out that every $10 increase in patient out-of-pocket costs led to lower adherence rates. This is particularly concerning amongst individuals with lower incomes and older adults as increasing prescription cost sharing can be associated with increased emergency department use, more frequent hospitalizations and other poor health outcomes.

These numbers illustrate at a high level how current market behaviors are having negative impacts on the system. PBMs operate in the middle of the entire distribution chain for prescription drugs and control all the rules. For example, they decide what pharmacies are allowed to fill medications for their members. Many times, for specialty and chronic medications, PBMs are mandating prescriptions be filled by pharmacies they own. In these situations, they get to decide what they pay themselves and, as we pointed out in our House Oversight and Accountability written testimony from May 23, 2023, that number can drive significant corporate profits while increasing costs for plan sponsors and their members.

Beyond this, they decide what medication a physician can and cannot prescribe and are increasingly excluding more and more medications from their formularies as called out by a January 10, 2023 article in Drug Channels. This article appropriately calls out the fact these exclusionary formularies are used "as a powerful tool for PBMs to gain additional negotiating leverage against manufacturers."

Additionally, there has been discussion about rebates and the relationship between the pharmaceutical manufacturers and PBMs. I am not here to defend or hold manufacturers harmless when we are talking about why we have a drug affordability issue in our country. They are by no means innocent, but the PBMs

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bear a significantly larger responsibility for the problem than they do. There are hundreds of brand manufacturers and only three main rebate aggregators. These three aggregators are each owned by one of the "big three" PBMs. They not only negotiate rebates for those traditional PBMs, but they now provide these rebate services to almost every other PBM in the industry. These aggregators are Ascent - created in Switzerland by Express Scripts in 2019 and now owned by Cigna, Zinc - created by CVS in 2020 and Emisar - started in Ireland in 2022 and owned by United Health Care. Ascent and Zinc each contract for over one hundred (100) million American lives and Emisar contracts for sixty five (65) million. They use their scale to create competition between manufacturers.

If a manufacturer does not negotiate a high enough rebate and ends up on the ever-expanding list of medications found on the exclusionary drug list, they will lose access to be able to sell their medications to tens of millions of lives. For this reason, they are forced to pay higher and higher amounts in total revenue to these GPOs in order to maintain their formulary placement. The difference between list price increases as defined by manufacturers and the manufacturers' net revenues after paying all rebates and discounts has been coined the gross-to-net bubble by Drug Channels. In their April 4, 2023 article, they point out this difference has grown from $167 billion in 2016 to $223 billion in 2022. While I do agree that manufacturers are increasing their prices, this is only half of the story. We can publicly see list price increases from the manufacturer. It is time for PBMs and their GPOs to list how much total revenue they obtain from pharma to show what the total net prices should be to plan sponsors and patients, but the PBMs continue to fight against this level of transparency.

Two specific examples point to how PBMs influence manufacturer pricing decisions. These examples also show how the upcoming flood of new biosimilars may not have a significant impact in reducing pharmacy costs as plan sponsors have been hoping for. Semglee is the biosimilar to the blockbuster diabetes medication Lantus. When the FDA originally approved Semglee in July 2021, the manufacturer Viatris indicated it would price a vial at about $98 – much below

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the price of $285 a vial for Lantus at the time. By November 2021, Viatris changed their strategy by offering two versions - a branded version of Semglee priced at $270 per vial (with a rebate) and an unbranded version at $98 with no rebate. Amgen watched this play out and when they became the first biosimilar to hit the market for Humira earlier this year they followed the same pricing strategy to have one with a 5% discount to Humira with a higher rebate and another version at a 55% discount with a much lower rebate. If you look at most PBM formularies, they have picked up the higher priced, higher rebate version on their formulary. This negatively impacts plan sponsors – who are not getting claim-level data to ensure they are getting the lowest cost option – and patients who are having to pay a higher amount for a more costly medication.

Finally, it will be important in future policy to call out how the term "rebate" is defined. The industry has pushed this concept of passing through 100% of their rebate dollars over the past few years. While a portion of the funds they get from manufacturers is contractually called a "rebate," the GPOs are adding an ever-expanding list of fees which PBMs keep as profit. See the example below for a list of those fees and whether they are included or excluded in the monies shared with plan sponsors. This list is an example of 3 unnamed industry PBMs. All sources listed should be considered rebate revenue, yet many PBMs exclude them in the monies shared with plan sponsors.

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Pharma Revenue Streams Included in Rebate Offer			
Source	PBM #1	PBM #2	PBM #3
Administrative Fees	Excluded	Excluded	Excluded
Clinical Program Fees	Excluded	N/A	Excluded
Consulting Fees	Excluded	N/A	Excluded
Credits	Excluded	Included	Excluded
Discounts	Excluded	Excluded	Excluded
Education Program Fees	Excluded	N/A	Excluded
Financial Incentives	Excluded	N/A	Excluded
Formulary Placement or Access Fees	Excluded	Included	Excluded
Implementation Fees	Excluded	N/A	Excluded
Market Share Based Payments	Excluded	Included	Excluded
Price Concessions	Excluded	N/A	Excluded
Promotional Allowances	Excluded	N/A	Excluded
Pull Through Program Fees	Excluded	Included	Excluded
Rebates	Included	Included	Included
Rebate Submission Fees	Excluded	N/A	Excluded
Software Licensing Fees	Excluded	N/A	Excluded
AWP Inflation Coverage	Excluded	Excluded	Excluded
All Other Payments From Pharma	Excluded	Excluded	Excluded

In closing, I would like to point to the *Consolidated Appropriations Act, 2021* (CAA). As pointed out in a article from Pharmaceutical Commerce in May 2023, the CAA has been designed to level the playing field between PBMs and plan sponsors. It will ensure that as a fiduciary to the plan all PBM revenue is disclosed, all data for that plan is shared with the plan sponsors, all compensation – both direct and indirect – brokers receive is fully disclosed and we will have a health care system that is more transparent and allows for more competition to drive down costs while improving quality and the lives of all Americans.

Thank you, members of the committee, for the opportunity to speak today and I look forward to your questions.

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For more information, here are links to articles aimed at educating purchasers about the PBM industry:

https://affirmedrx.com/how-gpos-work/

https://affirmedrx.com/how-pbms-make-money/

https://affirmedrx.com/what-is-a-pbm/

https://affirmedrx.com/8-things-every-employer-should-know-about-their-pharmacy-benefit-manager/

https://affirmedrx.com/how-do-pharma-pbm-contracts-play-role-in-rebate-leakage-part-1/

https://affirmedrx.com/how-do-pharma-pbm-contracts-play-role-in-rebate-leakage-part-2/

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House Committee on Oversight and Accountability
Role That Pharmacy Benefit Managers (PBMs) Play in the Pharmaceutical Market
May 23, 2023

Written Testimony of Greg Baker, BS Pharm
CEO of AffirmedRx

Chairman Comer, Ranking Member Raskin, and distinguished members of the House Committee, I would like to thank you for the invitation to speak to your committee on the necessity of PBM (Pharmacy Benefit Managers) reform in the United States.

My name is Greg Baker. I first and foremost am a pharmacist. I am also the CEO of AffirmedRx which is a transparent PBM I founded and is headquartered in Louisville, KY. I began my pharmacy career 30 years ago as a pharmacy technician for an independent pharmacy in Fort Wayne, IN that not surprisingly is no longer in business – for many reasons we will touch on today. Beyond that I have 11 years experience working directly with jumbo self-funded employers to help define and develop their pharmacy programs. Our goal at AffirmedRx is to partner with self-funded employers to deliver patient-centric pharmacy benefits with a mission to improve health care outcomes by bringing clarity, integrity and trust to pharmacy benefit management.

Currently, a handful of large PBMs control up to 80% of the market in the USA. This is problematic for every employer in the country. These PBMs are not constrained by any obligation to be transparent on their pricing or methodology and this has caused an extreme escalation of cost to all employers using a traditional PBM. This problem is also costing taxpayers significantly since some of the biggest health plans in the country are run by local, state and federal government entities. Medicare and Medicaid programs throughout the country are also deeply affected by the practices of traditional PBMs. And perhaps most importantly, it is also incredibly frustrating for practicing pharmacists who have a

professional duty and deep personal obligation to their patients to provide the best care possible and for the patients themselves who can no longer afford their medication which they need in order to live productive lives.

In August 2022 the American Bar Association published an article explaining trends and developments in price gouging at the state attorney general level. They define price gouging as the practice of raising prices of essential goods, services, or commodities to an unreasonable, unfair, or excessive level typically during a declared state of emergency. While only 37 states have price gouging laws other states can still bring about lawsuits as a violation of state consumer protection or similar laws. Most of these laws are only triggered by a declared state of emergency, the occurrence of a natural disaster, or an "abnormal market or economic disruption". I contend, based on current PBM practices and the state of the pharmacy industry in America, every attorney general should be actively pursuing pricing gouging lawsuits.

Let's consider some facts that make me believe we are in a state of emergency and at a minimum are dealing with "abnormal market or economic disruption".

- Medications can be a key component to reduce health risk, control chronic disease and treat illnesses. In the U.S., illness and death from non-optimized medication therapy cost $528.4 billion annually – equivalent to 16% of total U.S. healthcare expenditures
- Patients starting new prescriptions as prescribed by their physicians abandoned 94 million prescriptions at pharmacies in 2022 with increasing frequency as costs rise
- A JAMA article published in June 2021 suggest that while drug manufacturers may increase list prices in order to offer larger rebates to insurers, such increases were associated with increased out-of-pocket costs to patients

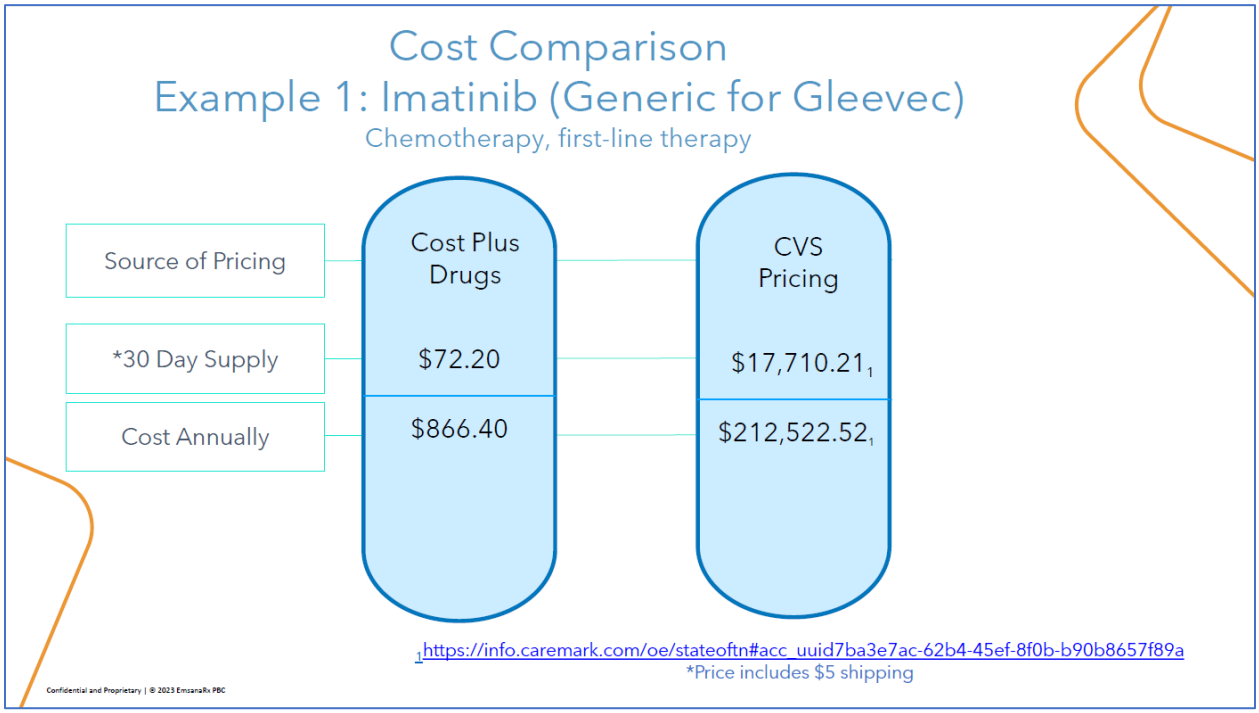
    - It found that between 2014-2018 list prices from manufacturers grew 13.3% while rebates paid to PBM's increased 24.4%.

- With the manufacturers raising list prices they also found that for every $1 increase in list price equated to an increase of $2.09 in patient out of pocket costs. While we have had much debate over the list price increases by pharmaceutical manufactures, these numbers clearly show how PBM's are retaining the most value and the American public continues to suffer greater drug affordability issues
- Finally, the report sadly pointed out that every $10 increase in patient out of pocket costs led to lower adherence rates. This is particularly concerning amongst individuals with lower incomes and among older adults as increasing prescription cost sharing can be associated with increased emergency department use, more frequent hospitalizations, and other poor health outcomes

While these numbers illustrate at a high-level overview how current market behaviors can have negative impacts on the entire system I have a specific example I would like to share with the committee. This points to the problem, but please understand this is just one out of the thousands of ways PBM's create profit for themselves at the detriment of our American society.

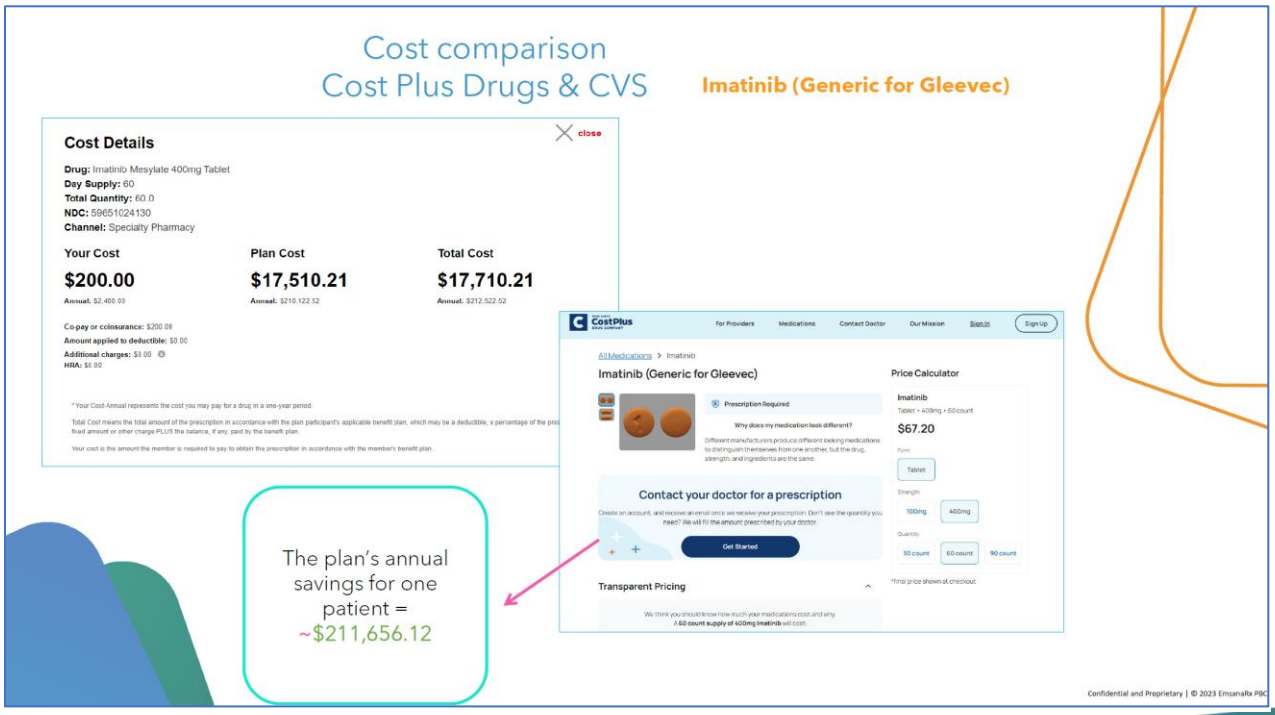
This example compares the cost of a medication provided transparently from Mark Cuban and his Cost Plus Drug Company. Mark posts all his invoices online so everyone can see what he is paying for the medications he sells. Traditional PBM's tell their clients they use their size and scale to get a better deal that smaller companies cannot compete with. We do know these large PBM's buy thousands of times more drugs than Mark Cuban and they very likely get a better acquisition cost, but they do not always use that purchasing power to help their clients. Below is one example which illustrates that the largest PBM's are likely making decisions in the best interest of their shareholder and not in the best interest of the patient. This is inexcusable at best in my opinion.

Figure 1



And the screenshots directly from each website…

Figure 2



These practices provide massive payouts to the traditional PBM while disadvantaging the employers and taxpayers utilizing their services. The worst part is the fact that this example exists because PBMs define where medications can and cannot get filled. In this situation they tell the market that because this is an oncology product it needs to be filled only at their own specialty pharmacy. Because the PBM – as a for-profit company – gets to decide what it pays itself bad things happen.

Additionally, there has been much discussion about rebates and the relationship between the pharmaceutical manufacturers and PBMs. I am not here to defend or hold manufacturers harmless when we are talking about why we have a drug affordability issue in our country. They are by no means innocent, but the PBMs bear a significantly larger responsibility to the problem. There are hundreds of brand manufacturers and only three main rebate aggregators. These three aggregators are each owned by one of the big three PBM's. They not only negotiate rebates for those traditional PBMs, but they now provide these rebates services to almost every other PBM in the industry. These aggregators are Ascent which was created in Switzerland by Express Scripts in 2019 and now owned by Cigna, Zinc which was created by CVS in 2020, and Emisar which was started in Ireland in 2022 and is owned by United Health Care. Ascent and Zinc each contract for over 100 million American lives and Emisar contracts for 65 million. They use their scale to create competition between manufacturers.

Let's look at insulin as there has been much talk about insulin pricing. Using Novo Nordisk as the example – they know if they lose access to the formulary controlled by one of these PBM's their medications will no longer be available to tens of millions of lives. So, the PBM's use this to their advantage and continue to extract more and more rebates because if Novo does not want to pay the higher rebate amounts the GPO will find one of the other manufacturers willing to do so. The massive market consolidation is why – as I previous mentioned – rebates are going up faster than list prices.

There are numerous reasons why costs go up, but the PBMs are at the heart of many of them. They are creating "abnormal market and economic disruption" at a time of national crisis when people can no longer afford their medications. When patients are not adherent to their medication overall health care costs increase significantly. If every American could afford their medication and had convenient access to a community pharmacy I believe we could remove hundreds of billions of waste for what we have today in a $1.4 trillion health care system. This price gouging and other negative practices need to be exposed and halted.

The practices being engaged in by these PBMs are inherently harmful to pharmacies throughout the country, especially independent pharmacies for several reasons. The first example of this is steering patients away from their local pharmacies to large mail-order organizations owned by these traditional PBMs themselves. Another example is these large PBMs also have the ability to make anything a "specialty drug" and not allow local pharmacies to dispense the drug regardless of what is best practice as shown in the Figure 2. Finally, even when these independent pharmacies are included in PBM networks, often the reimbursement of drugs to the pharmacy is less than their acquisition cost. In the end, this harms patients and their care. It is possible to operate a PBM, restrain costs for the employer and taxpayers while still providing the best pharmacy care available. But changes must be made to require greater transparency and allow for greater competition for this to happen.

While this testimony has illustrated numerous ways PBMs hurt American society there are unfortunately still many more. These include:

- Formularies are built preferring high-cost drugs over generics or drugs with lower cost
    - This results in high costs for members at the pharmacy counter when they are on high deductible or coinsurance plan
    - This increases PBM's profits via retention of manufacturer fees
- Narrow/Preferred networks are used to drive patients to more profitable pharmacy locations for the PBM while also limiting patient access which can be particularly harmful in lower income areas

- Self-funded employers are not allowed access to their pharmacy data which limits their ability to understand costs or make better decisions on behalf of their plan participants that could lower premiums and out of pocket costs
- Most self-funded employers use consultants they believe to be unbiased. These consultants may be compensated by the PBM with monies that are never disclosed to their clients – creating a conflict of interest and inhibiting competition. This concept is expressly called out in several SEC filings as illustrated on pages 22-23 of the 10-K filed by Willis Towers Watson calling out "market derived income"

In closing, I would like to point to William Deming who is acknowledged to be the foremost thought leader in total quality management. He has two disparate quotes I would like to leave the committee with. His first quote states "Every system is perfectly designed to get the results it gets". I know there has been much discussion that the PBM system is broken. My contention is that the industry has created a system to enrich corporate executives and create the opportunity to buy back hundreds of billions worth of corporate stock. This in turn massively increases shareholder value at the expense of the American corporation and taxpayer. The system isn't broken – it is working perfectly. The problem is we have the wrong system.

With that said I point to my second Deming quote. While we consider a better system through our conversation today Deming also said that systems need to be "a network of interdependent components that work together to try to accomplish the aim of the system. The aim for any system should be that everybody gains, not one part of the system at the expense of any other".
I commit to you that AffirmedRx will continue to work with employers, state and federal health plans and pharmacies throughout the country to find solutions to the challenges faced by those employers trying to just make sure their employees have access to the drugs they need while keeping down unnecessary costs.

Thank you, members of the committee, for the opportunity to speak today and I look forward to your questions.

For more information here are links to articles aimed at educating purchasers about the PBM industry:

https://affirmedrx.com/how-gpos-work/

https://affirmedrx.com/how-pbms-make-money/

https://affirmedrx.com/what-is-a-pbm/

https://affirmedrx.com/8-things-every-employer-should-know-about-their-pharmacy-benefit-manager/

https://affirmedrx.com/how-do-pharma-pbm-contracts-play-role-in-rebate-leakage-part-1/

https://affirmedrx.com/how-do-pharma-pbm-contracts-play-role-in-rebate-leakage-part-2/

To: Prescription Drug Affordability Board
From: Lissa Crider, retired, Bend, OR
Re: Eliquis
Date: 7/13/2024

I must take Eliquis 2 x daily. Even though I have a prescription plan that I pay monthly for, this drug is not covered so I pay full price. I would like to see a price reduction or a generic equivalent that is covered.

COMMUNITY ACCESS NATIONAL NETWORK

Mailing Address:

Attn: Jen Laws
PO Box 3009
Slidell, LA 70459

Chief Executive Officer:

Jen Laws
Phone: (313) 333-8534
Fax: (646) 786-3825
Email: jen@tiicann.org

July 17th, 2024
Oregon Prescription Drug Affordability Board
Department of Consumer and Business Services
350 Winter Street NE
Salem, OR 97309-0405

Dear Madam Chair and Honorable Members of the Oregon Prescription Drug Affordability Board,

About CANN: The Community Access National Network (CANN) is a 501(c)(3) national nonprofit organization focusing on public policy issues relating to HIV/AIDS and viral hepatitis. CANN's mission is to define, promote, and improve access to healthcare services and support for people living with HIV/AIDS and/or viral hepatitis through advocacy, education, and networking.

While CANN is primarily focused on policy matters affecting access to care for people living with HIV, we stand in firm support of all people living with chronic and rare diseases and recognize the very reality of those living with multiple health conditions and the necessity of timely, personalized care for each and every one of those health conditions.

Firstly, we thank you for the work you have done thus far and applaud your recent decision to pause affordability reviews and not pursue a work product for 2024. It shows your commitment to facilitating the best outcomes for all stakeholders, especially patients and consumers. In the June 2024 meeting, you engaged in a transparent and inclusive discourse regarding multiple concerns about the development of your 'reset'. We are writing today to contribute perspective for you to consider in your ongoing deliberations of rethinking your approach.

One of your most pertinent foundational expressed concerns is defining **affordability**. Being tasked with defining affordability for Oregonians, it is essential to note that affordability is a complex issue that encompasses so much more than the list price of a drug. Out-of-pocket costs for patients, pricing for PBMs, costs for payors, and entities vary significantly due to the complicated nature of discounts, rebates, and more. However, regarding patients and consumers, affordability is more encompassing than just price.

Affordability also entails access concerns. Consider a hypothetical example drug that costs five dollars for a prescription (assuming five dollars is not cost-prohibitive for a particular consumer). That drug costs more than five dollars if a patient's insurance requires that specific drug to be prescribed only by a specialist. The patient now has to wait for an appointment and pay for a visit to a specialist. If no geographically convenient specialist is available, the additional expense of travel and time is required to see the specialist. Conversely, consider the very real scenario of a drug prescription that does not result in profitability for the PBM associated with a patient's insurance. As such, that PBM places that particular drug on a higher formulary tier resulting in higher cost-sharing for the patient in addition to making it only available via specialty pharmacy. A patient may not have any specialty pharmacies that are easily accessible to them and/or may be forced to use the PBM's mail-order pharmacy, which comes with many challenges, including

continuity of care and lack of consistent patient-pharmacist communication. In the same vein, consider a drug where a UPL was set that was lower than the acquisition cost for a pharmacy. Pharmacies cannot afford to operate at a loss. Thus, in a particular geographic region, that drug would only be available at one or two pharmacies; therefore, patients would have to travel far to get to a pharmacy that carried what they needed. The aforementioned scenarios are just a few of the many lenses through which to view 'affordability.'

UPPER PAYMENT LIMITS (UPLs)

Drug affordability boards heavily focus on utilizing UPLs by statute and in practice. Two important foundational facts are that UPLs **do not** impact what manufacturers charge, **no**r do they change the acquisition costs that pharmacies have to pay to carry medication. Additionally, a recent study conducted by Avalere Health, a healthcare business consulting firm, involving feedback from executives from six different healthcare plans covering almost seven million people, showed that even insurers report UPLs will not reduce patient costs and will result in unintended negative consequences. A UPL only sets the maximum that insurance plans will reimburse for drugs. That is not a direct benefit to consumers because there is no mandate for plans to pass any realized savings on to patients, to retain medications with lower reimbursements, or for patients to be given lower cost-sharing requirements related to the medications. PBMs, not drug manufacturers, control and influence the costs and formulary construction, which directly affect the prescription financial burden of patients. The Federal Trade Commission released a report on July 9th detailing how PBMs inflate drug costs to boost their profits, to the detriment of patients and the overall healthcare system.

ATTACHMENT: Attached, you will find an "infographic" designed by CANN evaluating the potential impact of an "upper payment limit" on the state's AIDS Drug Assistance Program (ADAP – In Oregon, CAREAssist), particularly as it relates to the value of 340B rebates and their re-investment in "stretching scarce federal resources". While some commenters have previously dismissed the potential 340B impact by pointing to reduced acquisition costs under 340B, the value of 340B is found in the spread between reimbursement and a rebated acquisition cost. Reducing the reimbursement rate of **any** medication in which a 340B rebate is sought would necessarily reduce the value of the rebate – meaning safety net providers, not just the CAREAssist program, would be negatively impacted by the imposition of an upper payment limit (UPL). CAREAssist merely provides a "neat" and simplified example of a program which might be negatively impacted by a UPL.

We should note: Oregon does NOT contribute state dollars to CAREAssist. The program is exclusively funded by federal grant dollars for this purpose and further supported by 340B rebate revenues. Any imposition of a UPL would require the state of Oregon to either appropriate state dollars to the program *or* reduce services or persons served by the program due to decreased program revenue.

This example is not limited to CAREAssist. The impact would also be felt by federally qualified health centers and hospital systems in the state of Oregon. Similar to CAREAssist, the imposition of a UPL would require the state would to either appropriate dollars to fill the "gap" *or* readily tell residents that fewer medical services or locations might be the reality they face in the near future.

Furthermore, federal medical assistance percentages (FMAP) of matching federal dollars to state expenditures in Medicaid programs would similar be impacted by any imposition of a UPL. Oregon's FY2025 FMAP is 59% and federal multiplier is 1.44, meaning the state of Oregon pays less than half of the state's Medicaid budget, leveraging federal matching dollars to extend the program. This is particularly noteworthy because Oregon has taken advantage of matching federal dollars to benefit of patients and innovative programs. However, if a UPL is imposed, the state will be spending fewer dollars reimbursing medications and thus reducing state expenditure. For every one dollar "saved" for pharmacy benefit managers or managed care organizations administering Oregon's Medicaid program under the imposition of a UPL, at least two dollars will be lost to the Medicaid program's budget.

We understand these are not the intended consequences the Board or even Legislators might have considered when approaching "affordability" legislation, but they are the issues the Board must face and weigh. How "affordable" is it for patients or the state to divest from the laudable goals of these public programs and safety net provider entities?

ENGAGEMENT

CANN also applauds the board's desire to investigate and find robust ways to engage with patients, consumers, first-line medical professionals, community organizations, and more to gain first-hand perspectives of concerns around prescription affordability concerns. They appear to understand that claims data does not provide a thorough analysis of the patient experience nor the costs to systems. Claims data also does not capture information showing how much manufacturer rebates are passed on to patients or how much charitable private organizations and patient assistance programs help reduce patients' financial burden.

LEGISLATIVE REPORT

We understand that the actions of the board are significantly influenced by legislative statute. As you move forward, we encourage you to continue working with legislators to expand and modify the parameters in which the Board can utilize methodologies and desired information gathering to achieve its goals. Moreover, we encourage you to investigate other means of attaining the affordability goals you formulate, without the negative, unintended consequences UPLs pose. The state of Colorado's PDAB, in its legislative report, did heed advice offered from CANN and other patient advocates in elevating concerns related to plan design, patient protections regarding utilization management, and requested the legislature work to understand how rebate values are not sufficiently passed along to patients. We similarly encourage Oregon's PDAB to offer these meaningful and tangible potentials to the legislature.

CANN looks forward to working the board, sharing our experiences from other states regarding PDABs, and ensuring the best outcomes for patients remains a priority.

Respectfully submitted,

Ranier Simons
Director of State Policy

On behalf of
Jen Laws
President & CEO
Community Access National Network

COMMUNITY ACCESS NATIONAL NETWORK

Prescription Drug Advisory Boards (PDABs)

Response Project for People Living with HIV

Prescription Drug Affordability Boards: A Threat to Ending the HIV Epidemic?

State AIDS Drug A33i3tance Program3, or ADAP3, are largely dependent on 3aving3 and revenue3 1rom the 34OB Drug Pricing Program to *"stretch scarce Federal resources as tar as possible reaching more eligible patients and providing more comprehensive services."*

Prescription Drug AVordability Boards, or PDABs, are considering "price control3" to set the cost of prescription drugs by setting an "upper payment limit" (UPL).

But here are some facts on why UPL price controls are bad for providers...and patients:

- 340B's value is found in the "spread" between the reimbursement rates and a reduced acquisition cost by way of drug manufacturer 340B rebates
- Reducing reimbursement rates by way of an "upper payment limit" will reduce the value realized by 340B rebates
- Providers end up with less money, which means they can afford to fund less services
- That's only *IF* a pharmacy can still afford to fill the medication
- Will your copay change" NO

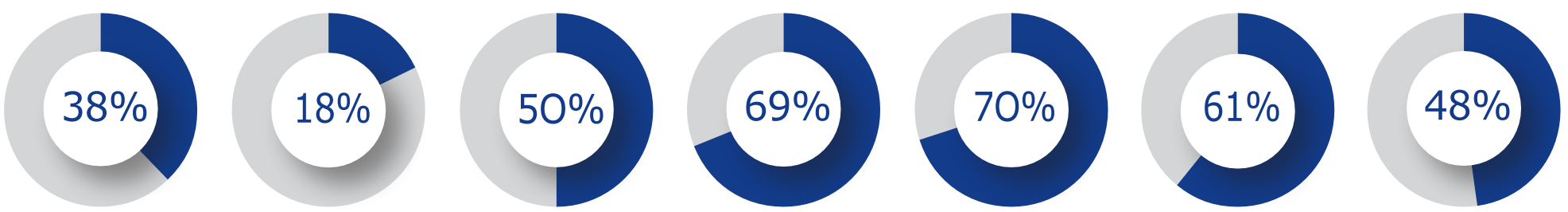
Ex.
Antiviral B Hypo:
- Normal reimbursement: $550
- 340B Price: $50
- Value of rebate: $500 - to be reinvested in HIV programming/providing medications

Under a UPL:
- UPL reimbursement: $350
- 340B Price: $50
- Value of rebate: $300 - to be reinvested in HIV programming/providing medications

What happens if the UPL is set below the cost of the medication?

Will your pharmacy be able to 1ill it?

This is particularly striking when we think about State ADAP Budgets, and NASTAD's 2023 RWHAP Part B ADAP Monitoring Report provide3 in3ight3. Take a look:



Mational Total	Colorado	Connecticut	Michigan	Mew Jersey	Oregon	Washington State
ADAP Funding (or about $802.66M)	SDAP (or about $3.9M)	(or about $16M)*	(or about $29M)*	(or about $66.1M)*	(or about $5.8M)*	(or about $11.7M)*

* ADAP State Contribution = $0

● = % of budget that is rebate

According to NASTAD, for most states, a majority of ADAP clients live at or below 300% of the Federal Poverty Level, meaning even when they're Medicaid Qualified, they still need help. Taking dollars out of ADAP by reducing the value of the rebates is a DISINVESTMENT 1rom HIV-related 1unding.

For more information, visit our website at www.tiicann.org/pdab-project.html

On behalf of HealthHIV, we genuinely appreciate the opportunity to provide comments on the Board's input on cost considerations—which includes the meaning of affordability, utilizing continuous quality and program evaluation metrics, and potential changes in access.

For background, HealthHIV is a national non-profit organization that works with healthcare organizations, communities, and providers to advance effective HIV, HCV, STI, and LGBTQI+ healthcare, harm reduction, and health equity through education and training, technical assistance and capacity building, advocacy, communications, and health services research and evaluation.

Implications of Upper Payment Limits Setting UPLs may seem like a straightforward solution to controlling drug costs, but it can lead to significant challenges in patient care. For instance, imposing a ceiling on reimbursement rates can discourage pharmacies and clinicians from offering certain medications if they are not adequately compensated. This can limit patient access to essential treatments and force individuals to seek care elsewhere, disrupting continuity and potentially leading to worse health outcomes and ultimately more cost to the system, including those the Oregon PDAB aims to improve. This is particularly concerning in the context of pharmacy deserts, where the closure of pharmacies can severely limit access to medications for underserved communities.

Operational Challenges and Financial Burdens Implementing UPLs could introduce numerous operational challenges and financial burdens across the drug supply chain, including for pharmacies, wholesalers, providers, payers, and patients. For example, effectuating a UPL price through the supply chain may require new pharmacy and wholesaler acquisition/tracking systems and introduce payment streams that do not exist today. Any challenges in pharmacy and wholesaler supply operations can directly lead to gaps in patient access, particularly if a patient's local pharmacy is unable to operationalize and comply with UPL-driven requirements.

Payers have indicated that drugs subject to UPLs, or other drugs in their therapeutic class, could face more utilization management (e.g., prior authorization) once a UPL is implemented, as well as changes in formulary tiering, which could increase patients' out-of-pocket costs. UPLs are also likely to have long-term effects on the prescription drug ecosystem, including provider access, copay assistance needs, and manufacturer research and development (R&D).

Issues with Step Therapy The use of step therapy protocols, where patients must try alternative medications before accessing their prescribed treatment, poses serious risks. These protocols often do not account for individual medical histories and can delay access to the most effective treatments. For patients with chronic conditions, such delays can result in deteriorating health and increased overall healthcare costs. While step therapy aims to control costs, it can ultimately create more downstream expenses due to complications arising from ineffective initial treatments.

Impact of Pharmacy Deserts on Patients and Links to Affordability One important consideration in establishing UPLs is the trend of pharmacy closures that disproportionately affect rural and underserved urban areas, creating pharmacy deserts. These closures are often exacerbated by pharmacy benefit managers (PBMs) routing patients to their preferred or contractual pharmacies. This can significantly stymie and create more inequitable access to medications, especially for those who rely on local, long-standing community pharmacies for their prescriptions and their localized approach to care and prevention. Without nearby preferred or trusted patient pharmacies, residents may face longer commutes, reduced access to medications, and increased time or out-of-pocket costs.

Additionally, patients might be routed to their plan's preferred pharmacy, which may stop carrying medications subject to UPLs, or they may have a harder time obtaining adjusted medications that replace those under UPL considerations—medications that have also been subject to UPL scrutiny across other states' PDABs. Addressing this issue requires innovative solutions, such as enhancing Medicaid reimbursements for low-volume pharmacies, incentivizing pharmacies to operate in underserved areas, and improving transparency around PBMs to ensure fair pricing and support for independent pharmacies. UPLs without these considerations can jeopardize the good work you've all already done.

Recommendations To ensure that the Board's efforts effectively balance cost control with patient care, we recommend the following:

1. **Review and Refine Methodologies:** More thoroughly review and refine the methodologies and CQI data (including real-world data) used in affordability evaluations to ensure decisions are based on more accurate and comprehensive information.

2. **Involve Stakeholders:** Engage a broader range of stakeholders—including patient advocacy groups, healthcare providers, and pharmacists, to gather diverse perspectives and address potential gaps in the current evaluation process. The efforts to date have yielded good success, and that should be carried forward.

3. **Ensure Patient Access:** Develop clear and robust exception processes within utilization management (specifically fail-first and step therapy protocols) as related to UPLs in efforts to more solidly protect patient access to essential health treatments and prevent adverse outcomes, like gaps in treatment.

4. **Enhance Data Transparency:** Improve the transparency of data analysis and the incorporation of patient input to ensure decisions reflect real-world patient experiences and costs.

5. **Address Pharmacy Deserts:** Implement policies to prevent pharmacy disruptions and deserts in underserved areas, such as enhanced Medicaid reimbursements for low-volume pharmacies, incentives for pharmacies in rural and urban underserved areas, and transparency in PBM practices to ensure fair pricing and support for independent pharmacies. Do this in concert with your current work.

By adopting these recommendations during the Board's "pause" it can better navigate the complexities of drug pricing and access, ensuring that cost control measures do not inadvertently harm our healthcare system.

Thank you for considering our input.

Thoughtfully—*and respectfully*—submitted for your consideration,

Scott D. Bertani

Director of Advocacy, HealthHIV

July 25, 2024

OR Prescription Drug Affordability Board
Department of Consumer and Business Services
350 Winter Street NE
Room 410
Salem, OR 97309

Dear Members of the OR Prescription Drug Affordability Board:

On behalf of the Arthritis Foundation, representing the nearly 60 million Americans and over 833,000 Oregon residents living with doctor-diagnosed arthritis, we would like to submit comments following the Prescription Drug Affordability Board (PDAB) meeting July 24, 2024.

Many important questions and themes were discussed during the July 24 meeting, including the impact of both state and federal health system policies on patient affordability. A good example would be the recent passage of HB 4113 that ensures copay assistance counts towards a patient's out of pocket costs. When implemented, this protection will greatly impact affordability for many patients. We believe it is important for the PDAB to consider this law in relationship to the other criteria it is considering for determining affordability, in addition to the overall question of affordability to the patient.

We also want to raise some questions about the design and establishment of an Upper Payment Limit (UPL), which could have wide-ranging implications. While the Arthritis Foundation does not take a formal position on UPLs, we do have a number of questions about how a UPL would be designed and operationalized, including:

1. What methodologies would the PDAB consider in determining a UPL?
2. How would the PDAB ensure any methodology is patient-centered and accurately incorporates patient experiences and preferences?
3. How would the PDAB engage with the patient community in the design of the UPL?
4. Once implemented, how would the UPL affect other drugs in the class and the designation of preferred and non-preferred drugs?
5. How can the PDAB ensure that a UPL does not negatively impact access to Enbrel and the ability of Enbrel to remain on formularies?
6. Has the PDAB considered unintended consequences such as increased utilization management and the potential for patients to be inappropriately switched to a less effective drug?
7. What is the potential impact on other pricing structures, including Medicaid Best Price and 340B calculations?

8. What is the potential impact to providers and pharmacists in terms of reimbursement for stocking and/or administering the drug?

We would also caution that establishing a UPL will not necessarily make a drug more affordable for a patient. Insurance design and employer benefit packages are such that many patients are on high deductible health plans (often with no other option) and specialty drugs like Cosentyx are often placed on specialty tiers with co-insurance. For Exchange plans, it is not uncommon for co-insurance to reach 40-50%. Even if you set an UPL that is half the current list price, a 40% co-insurance will still make that drug unaffordable to most patients without some form of cost-sharing assistance.

With regard to methodology, we have developed several sets of principles and best practices regarding patient-centered value assessment methodologies and would highlight in particular a project in which we collaborated with the Innovation and Value Initiative (IVI) to better incorporate patient experience data into their modeling. We coordinated a focus group that yielded invaluable insights and as a result we co-authored a white paper highlighting the key themes and best practices for this patient-centered approach. While we have included this in previous comments to the OR PDAB, we are reiterating some of the key highlights here, as we believe these conclusions are critically important to take into consideration.

- Traditional clinical trials and research do not always capture the full complexity of living with RA, including comorbid conditions, fatigue, mental health, and the impact of hormonal changes.
- Access to effective treatment may be driven by insurance coverage or haphazard testing of treatments rather than by clinical guidelines.
- Costs related to RA include far more than direct medication costs and need to be captured.
- While RA is a progressive disease, people living with it are seeking independence and normalcy versus just symptom management.

The focus groups revealed a diverse range of experiences. From the paper:

- While severity of RA and response to treatment vary among individuals, commonly experienced symptoms include significant joint pain and weakness, stiffness, and fatigue.
- Most participants described fatigue as an unaddressed impact of RA, and a factor further exacerbated by many of the RA treatments as a side effect.
- Multiple individuals pointed to hormonal changes (puberty, pregnancy, menopause, etc.) as “triggers” to the onset of symptoms or treatment failures.

- Nearly every participant described significant psychological impacts of the disease, including depression, anxiety, and social isolation.
- Co-occurring conditions are common, and when present, complicate outcomes. Multiple participants reported co-occurring health conditions, including type 1 diabetes, fibromyalgia, spondyloarthropathy, lupus, anxiety, and depression.

The paper noted that even with only 14 participants, there was wide diversity in time to diagnosis (between 6 months and 5 years) and time to finding an effective treatment (between 1 year and never); treatment experiences from the paper:

- Participants reported that treatment choices appeared to be based on trial and error or insurance coverage, rather than clinical guidelines or assessment by their clinician.
- Many had difficulty finding effective treatment over time. Most were concerned about the durability of treatment and the lack of clarity about what might trigger sudden change or failure of a treatment. Several reported never finding a fully effective treatment option despite extensive regimen testing.
- Multiple individuals were concerned about running out of treatment options; there was a sense that each treatment had a “shelf life” or limited time horizon.
- Participants reflected a common experience or understanding that insurance coverage, socioeconomic status, and race impact the quality of and access to treatment.
- Participants described the impact of treatment on choices to have children, how having children impacts treatment options, and the ability to have children.

Also from the paper:
Other areas of less frequently measured costs that have high impact on patients’ experiences and outcomes include:

- Time spent in seeking, receiving, and recovering from treatment, with some calculating this cost to be upwards of a month a year.
- Diminished ability to work and lost wages due to early retirement or career impact, including choosing lower paying jobs to ensure health insurance access.
- Heavy burden of RA on caregivers (spouses, parents, and siblings), such as anxiety, missed work time, childcare, and job choice based on health insurance.
- Ancillary costs of seeking and receiving treatment, including transportation costs, non-medical supportive expenses (e.g., assistive devices), and non-covered benefits.

As you continue your work, we urge you to meet directly with patients to gain a more comprehensive understanding of the factors that contribute to their ability to access and afford their medications, and to work directly with patient groups like ours to design an appropriate, patient-centered methodology. Thank you for your consideration, and we look forward to engaging with you in the future.

Sincerely,

Melissa Horn
Director of State Legislative Affairs
Arthritis Foundation
MHorn@arthritis.org

National
Multiple Sclerosis
Society

July 26, 2024

Oregon Division of Financial Regulation
Oregon Prescription Drug Affordability Board
350 Winter St. SE
Salem, OR 97309

RE: National Multiple Sclerosis Society follow up Upper Payment Limits, Constituent Panels discussion

Dear Members of the Oregon Prescription Drug Affordability Board:

Thank you for taking the time to gather all stakeholders for the constituent panels discussion meeting regarding upper payment limits on July 24. The opportunity to provide direct feedback to the board from the patient perspective is much appreciated. This letter is to provide additional context and clarity to the National Multiple Sclerosis Society (the Society) comments related to upper payment limits.

UPLs related to copays and MS infusible products
The Society views the establishment of upper payment limits (UPL) as creating the potential to lower out of pocket costs for patients. High out of pocket costs are typically due to co-insurance, which is when the patient must pay a percentage of the wholesale acquisition cost (WAC) or list price as opposed to a flat copay amount. This is especially true for MS disease-modifying therapies (DMTs). A lower UPL would in turn create lower out-of-pocket costs for those who must pay co-insurance. Very important to note is that for infused medications, which include several of the most prescribed MS DMTs, patients face significant additional costs from the administration of, and additional services attached to, an infused product. A UPL would not affect this additional expense and, as a result, might not substantially lower patient out-of-pocket costs brought on by the overall infused medication services.

Costs of MS DMTs
When we discuss the cost of MS DMTs, we are not just talking about products new to the market. There are now over 20 DMTs on the market to treat relapsing-remitting courses of MS. 12 have been on the market for at least a decade, some of those have been on for even longer. The first DMT came onto the market in 1993 and was priced at approximately $11,000 annually. That same drug today has a WAC of over $126,000. It has not had any major formulaic changes. When researching the high cost of medications and the opportunity for review, we should keep in mind products such as these that are seeing continuous price increases year over year well above the rate of inflation with no true explanation.

The MS Society knows that price of the medication is but one aspect of what makes access to these high-cost prescriptions out of reach for many people with MS and other conditions. The Society will

National
Multiple Sclerosis
Society

continue to look at the entire healthcare system and encourages legislatures and boards, like the Oregon PDAB, to continue to work to address other aspects of the prescription drug supply chain that get in the way for patients, like continued attention to, and reform of, pharmacy benefit managers (PBMs) and utilization management protocols.

Respectfully,

Seth M. Greiner
Senior Manager, Advocacy
Seth.Greiner@NMSS.org

July 29, 2024

To whom it may concern:

I am a 3rd generation pharmacist/pharmacy owner and have practiced retail pharmacy for nearly 30 years. I welcome the opportunity to participate in this discussion regarding prescription drug affordability here in Oregon. I echo some of the comments that were made during the July 24, 2024 board meeting by other panelists. I feel that it would be helpful at similar panelist meetings in the future to have the intended questions shared with the panelists prior to the meeting so that we may be better prepared to answer them more accurately and it may make the flow of the meeting more efficient. I would also like to say that there seemed to be very little time for all of the panelists to comment if they had wanted to do so. I understand that with so many panelists invited to this meeting, it may be unrealistic to host a meeting for the length of time necessary to achieve this. I do applaud the PDAB for inviting so many stakeholders to this meeting.

I am concerned that any Upper Payment Limit (UPL) implemented may not make much of an impact with the current payment/reimbursement model. I am aware that rebates and other fees are involved with the Pharmacy Benefit Managers (PBMs) negotiation structure for placing medications (especially brand medications) on their formularies. PBMs' negotiating places higher cost drugs in a preferred status on many plans. Brett Michelin of Accessible Medicines identified that higher cost drugs are being purchased when less costly products are available on the market.

The patient and the public at large are shielded from the actual cost of medicine. As Brian Warren from Biotechnology Innovation Organization stated, what a patient pays at the pharmacy would define affordability for the general public. If prescription medications are not affordable to the pharmacy purchasing and dispensing them or if the pharmacy is not reimbursed at rates that would cover the overhead involved in filling them, then affordability of the medications for the patient are less of an issue than accessibility of the medications.

If pharmacies would be paid appropriately, as described above, and spread pricing (e.g., the pharmacy is paid $20 for a Rx and the PBM customer, such as the government or employer, is charged $80 for the same Rx) is removed from the current payment structure, then the bottle neck or path of greater resistance would not be at the pharmacy level. I feel that if accessibility if not an issue, then UPLs would be easier to implement.

One of the board members voiced that it seemed that some of the panelists were more concerned about protecting themselves than addressing the issue of medication affordability. It is almost too complex and interconnected to separate these out for some of us panelists.

During the meeting, I was very interested in hearing that 11 other states had implemented the type of policies that Oregon's PDAB is exploring. I would think it would be of great benefit to find out what these other states have implemented and what the results of those implementations have been (the good, the bad, and the unexpected).

Thank you for your attention and willingness to listen. I hope that it has been of some help.

Thomas Wade Irby, RPh
Irby Pharmacy