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Oregon Prescription Drug
Affordability Board

Prescription Drug Affordability Board (PDAB) Upper Payment Limit (UPL) Draft Board Report

October 2024

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Executive Summary

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Background

The Prescription Drug Affordability board (PDAB or the board) was established in the Department of Consumer and Business Services (DCBS) and is committed to protecting residents of Oregon, state and local governments, commercial health plans, health care providers, pharmacies licensed in Oregon, and other constituent groups within the Oregon health care system from the high costs of prescription drugs. The board was established by the legislature in 2021 under Senate Bill (SB) 844, later codified in Oregon Revised Statute (ORS) 646A.693.[1] The board provides policy recommendations and reports to the Oregon Legislature. These materials include a report issued each December with legislative policy recommendations for making prescription drugs more affordable within the state's healthcare system. The board also produces an annual legislative report that address issues relating to generic drugs.

The responsibilities of the board include conducting affordability reviews to identify nine drugs and at least one insulin product that it determines may create affordability challenges for health care systems or through high out-of-pocket costs incurred by Oregonians. Oregon Administrative Rules include the criteria to be used in conducting affordability reviews on prescription drugs and insulin products.[2] Through the authority granted under SB 192 (2023), the PDAB is developing a plan for establishing upper payment limits (UPLs) on drugs sold in the state of Oregon that are subject to affordability reviews under ORS 646A.694.[3,4]

In December 2023, the board, acting through the Department of Consumer and Business Services, Division of Financial Regulation, contracted with Myers and Stauffer (PO-44000-00028053) to provide prescription drug consulting and outreach services related to the board's SB 192 obligations. As part of these services, Myers and Stauffer conducted focus group meetings with constituent groups as identified and approved by board staff, including the Public Employees' Benefits Board (PEBB), Oregon Educators' Benefits Board (OEBB), carriers, consumer organizations, hospitals, retail pharmacies, 340B covered entities, pharmaceutical manufacturers, pharmacy benefit managers, and patient advocacy groups. After each focus group meeting, Myers and Stauffer compiled a summary document and then created a final report identifying any critical discussions, recommendations, or strategies that arose from the constituent group engagement meetings. The board also contracted with Horvath Health Policy to provide consultant services. Their work is referenced throughout this report and included in the appendices.

More information on the board's mission, meetings, decisions and reports may be found on the PDAB website (https://dfr.oregon.gov/pdab/Pages/index.aspx).

Oregon PDAB's Prior Work

The Oregon Legislature created the board in 2021 due to concerns about rising prescription drug costs and their negative effect on patients and the health system in the state. The board met for the first time on June 23, 2022 and convened eight times in 2022, 12 times in 2023, and is set to meet 11 times in

[1] S.B. 844, 81st Leg. Assemb., Reg. Sess. (Or. 2021) https://olis.oregonlegislature.gov/liz/2021R1/Downloads/MeasureDocument/SB844.

[2] OR. ADMIN. R. 925.200.0010 – 925.200.0020 https://dfr.oregon.gov/pdab/Documents/PDAB-1-2023-affordability-review-rule.pdf.

[3] Oregon Prescription Drug Affordability Board website. Frequently Asked Questions. https://dfr.oregon.gov/pdab/Pages/pdab-faqs.aspx, accessed 4/2/2024.

[4] Senate Bill 192 (2023) https://olis.oregonlegislature.gov/liz/2023R1/Downloads/MeasureDocument/SB192/Enrolled, accessed 4/2/2024.

2024. Board members started immediately working on the road map provided in its founding legislation. An early task was to study the entire prescription drug distribution and payment system and the generic drug market. The board presented its first report to the Legislature in December 2022, which contained recommendations for the Oregon Legislature including: (1) implementing a UPL; (2) promoting transparency in supply chain rebate; (3) expanding reporting requirements for patient assistance programs (PAPs); and (4) expanding reporting to more insurers for the Drug Price Transparency (DPT) Program.[5] These recommendations were later proposed as part of SB 404 in the 2023 legislative session. In June 2023, the board presented its second annual generic drug report to the Legislature that reviewed generic spending, drug shortages, price fixing, pay for delay, spread pricing, market disrupters, and cost savings from biosimilars. Also in 2023, the board drafted a legislative report of policy recommendations. The report included three policy recommendations: (1) lower insulin co-pay limit to $35 and/or decouple from inflation index; (2) Change Oregon's statute language regarding substitution requirements for biological products and biosimilars; and (3) expand pharmacy benefit managers (PBMs) reporting requirements for more transparency. In 2024, the board submitted its third annual legislative report on generic drugs. The 2024 generic drug report evaluated the use of generic drugs to lower the cost of medications for consumers and the health care system.

The board approved policies to guide its work when it was first established in June 2022. Each year, the board reviews the policies and amends them if needed. These policies address board administrative requirements including but not limited to board composition, board member terms, quorum, conflict of interest, and public comment. The board may also adopt rules in accordance with applicable provisions under ORS Chapter 183 including authority to adopt criteria for drug affordability reviews and to provide consultation to DCBS in the adoption of annual fees to be paid by manufacturers to meet the cost of program and board administration costs. During the rulemaking process the public is encouraged to submit comments to provide feedback by signing up for and attending board meetings and hearings. In December 2022, the board adopted the Oregon model Rules for Rulemaking and Public Records Requests. This permanent administrative order provided a legal framework for the board to engage in rulemaking as authorized by ORS 646A.964 and SB 192.

Drug Affordability

The pace of retail prescription drug spending in the United States has varied in recent decades. According to the most recent national health expenditures (NHE) accounts compiled by the Centers for Medicare & Medicaid Services (CMS), the United States spent $405.9 billion on prescription drugs in 2022—approximately 9.02 percent of total health consumption expenditures.[6] Of this figure, $43.8 billion was attributed to Medicaid—approximately five percent of total Medicaid expenditures.[7] Additionally, 32 percent of prescription drug spending, or $378 billion, is attributed to Medicare, and 42

[5] OR PRESCRIPTION DRUG AFFORDABILITY BOARD, 2022 REPORT FOR THE OREGON LEGISLATURE (Dec. 19, 2022) https://dfr.oregon.gov/pdab/Documents/reports/PDAB-Report_2022.pdf.

[6] CMS.GOV, NHE FACT SHEET (2024) https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet#:~:text=Historical%20NHE%2C%202020%3A,20%20percent%20of%20total%20NHE.

[7] Elizabeth Williams, et al., *Recent Trends in Medicaid Outpatient Prescription Drug Utilization and Spending*, KFF (2023) https://www.kff.org/medicaid/issue-brief/recent-trends-in-medicaid-outpatient-prescription-drug-utilization-and-spending/#:~:text=Spending%20Trends,-Net%20spending%20(spending&text=Gross%20Medicaid%20spending%20(spending%20before,gross%20spending%20is%20drug%20rebates.

percent is attributed to private health insurance.[8] By 2028, overall prescription drug spending is projected to increase to $560.3 billion, and Medicaid spending on prescription drugs is projected to increase to $57.6 billion.[9] Importantly, this data does not include drugs administered in clinics or hospitals such as gene therapies, which are generally very expensive.

Opacity surrounding drug pricing and reimbursement practices obscures understanding and accountability for the cost of drugs. This lack of transparency underscores a pressing need for comprehensive reforms to ensure affordability, fairness, and efficiency within the pharmaceutical landscape. States throughout the nation have taken legislative action in an attempt to control drug spending while increasing pricing transparency, including the creation of PDABs to review the affordability of certain drugs and make policy recommendations on how to control state spending.

Transaction Relationships in the Supply Chain

At its highest level, the phrase "drug supply chain" is used to describe the process of delivering prescription medications from the manufacturer to the ultimate end user, the patient. The pharmaceutical supply chain is complex, involving two concurrent streams: the flow of product and the flow of payment. Within these flows exists an intertwined and complex system of participants. This discussion focuses on the delivery of medications in an outpatient setting, specifically those drugs delivered through retail, mail order or specialty pharmacies, and drugs administered on an outpatient basis through a clinic or physician's office. The system is made further complex with the addition of the purchasing streams for inpatient and nursing facility medications. This discussion is not intended to describe in detail the further complex interactions of the individual markets (brand, generic, biologic, and biosimilar drugs). The outpatient focus of this discussion reflects the expected nature of the drugs that would be most likely to be evaluated for action by the PDAB. The groups involved in the supply chain mirror those included in the constituent and consumer group discussions:

- **Manufacturers.** Manufacturers hold the approval from the Food and Drug Administration (FDA) to produce and/or sell the prescription drugs. They also manage the actual distribution of drugs from manufacturing facilities to drug wholesalers, and in some cases, directly to retail pharmacy chains, mail-order and specialty pharmacies, hospital chains, physician offices, and some health plans.[10]
- **Distributors/Wholesalers.** Wholesalers purchase pharmaceutical products from manufacturers and sell them to a variety of customers, including pharmacies (retail, mail-order, and specialty), hospitals, and long-term care and other medical facilities (e.g., community clinics, physician

[8] Juliette Cubanski, et al., *What to Know about Medicare Spending and Financing*, KFF (2023) https://www.kff.org/medicare/issue-brief/what-to-know-about-medicare-spending-and-financing/#:~:text=Medicare%20plays%20a%20major%20role,drug%20sales%20(Figure%201). Juliette Cubanski et al., *How does Prescription Drug Spending and Use Compare Across Large Employer Plans, Medicare Part D, and Medicaid?*, KFF (2023) https://www.kff.org/medicare/issue-brief/how-does-prescription-drug-spending-and-use-compare-across-large-employer-plans-medicare-part-d-and-medicaid/#:~:text=Among%20all%20payers%2C%20private%20health,of%20total%20retail%20drug%20spending.

[9] Id.

[10] The Health Strategies Consultancy LLC, *Following the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain*, The Kaiser Family Foundation, Mar. 2005, https://tinyurl.com/2p9a38p6.

offices, and diagnostic labs).[11] They also resell to smaller, regional distributors for regional or local distribution to retail pharmacies and hospitals.[12]

- **Pharmacy Benefit Managers (PBMs).** PBMs manage prescription drug benefits on behalf of health plans and payers. PBMs design and maintain drug formularies to encourage patients and prescribers to use certain drugs in exchange for post-utilization price concessions. Price concessions from manufacturers are paid to PBMs via rebates, a share of which are passed back to payers, and which ultimately could result in lower premiums or other benefits for insured patients. Generally, PBMs do not buy or sell medicines, although this is starting to change with PBMs establishing their own private label to sell drugs that no longer have federal law protections from market competition. Separately, PBMs maintain networks of pharmacies, including pharmacies owned by the PBM's parent company and/or owned by the PBM directly.[13] PBMs also serve as gatekeepers to patient access/utilization through utilization management policies such as prior authorization.
- **Payers.** Payers are health insurers, large employers, and government programs that offer drug coverage to individuals. Payers include employers offering health plans to their employees, commercial insurers selling health plans to employers and individuals, and government programs such as Medicare, Medicaid, and state and local government employee benefit plans.[14]
- **Pharmacies.** Pharmacies purchase drugs from wholesalers, and occasionally directly from manufacturers, and then take physical possession of the drug products. After purchasing pharmaceuticals, pharmacies assume responsibility for their safe storage and dispensing to patients. Pharmacy operations include maintaining an adequate stock of drug products, providing information to consumers about the safe and effective use of prescription drugs, and facilitating billing and payment for consumers participating in health plans.[15] Pharmacies are often are owned by large vertically-integrated corporations that include PBMs, insurers, and medical provider organizations.
- **Group Purchasing Organizations (GPOs).** GPOs allow independent pharmacies and small pharmacy chains to join together to leverage combined purchasing power to negotiate discounts with manufacturers, wholesalers, and other vendors.[16] GPOs are used extensively in the hospital and health care system markets to negotiate discounts on drugs, and other supplies and services. GPOs do not take physical possession of drug products.[17] These purchasing organizations should not be confused with PBM-owned entities that are also called GPOs; PBM-

[11] Id.

[12] National Academy for State Health Policy, *A Glossary of All Terms Pharma,* June 15, 2018, https://nashp.org/a-glossary-of-all-terms-pharma/.

[13] *Pharmacy Benefit Managers and Their Role in Drug Spending*, The Commonwealth Fund, (Apr. 22, 2019), https://tinyurl.com/uvdfeynf.

[14] Andrew W. Mulcahy & Vishnupriya Kareddy, *Prescription Drug Supply Chains*, Rand Corporation, (2021), https://www.rand.org/pubs/research_reports/RRA328-1.html.

[15] The Health Strategies Consultancy LLC, *Following the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain*, KFF, (Mar. 2005), https://tinyurl.com/2p9a38p6.

[16] *The Evolution of Group Purchasing* Organizations, Drug Topics, (Oct. 10, 2016), https://www.drugtopics.com/view/evolution-group-purchasing-organizations.

[17] Andrew W. Mulcahy & Vishnupriya Kareddy, Prescription Drug Supply Chains, Rand Corporation, (2021), https://www.rand.org/pubs/research_reports/RRA328-1.html.

based GPOs function as rebate aggregators and engage directly with manufacturers to negotiate rebate and other contracts.[18]

- **Pharmacy Services Administrative Organizations (PSAOs).** PSAOs represent and provide services for independent or small chain pharmacies. Services offered can include negotiating and entering into PBM contracts on the pharmacy's behalf, providing the pharmacies with communications and information regarding contractual and regulatory requirements, and providing general, claim-specific assistance by means of a help desk or dedicated staff person.[19] PSAOs are often owned by wholesalers or PBMs.[20]
- **Patients**. Patients, may also be referred to as "consumers", "enrollees", or "beneficiaries". Their access to prescription medications and financial responsibility for payment are governed by a variety of factors including health plan formulary placement, plan benefit design, and most importantly, whether or not they have access to a health plan or prescription drug plan. Typically, lower out-of-pocket costs and fewer utilization management requirements are applied to preferred drug lists or PBM alternatives. The type and magnitude of out-of-pocket payments vary depending on benefit design.[21]

Any conversation about the drug supply chain must recognize the influence of manufacturer-paid rebates on the distribution of drugs. The majority of rebate payments occur between manufacturers and PBMs, although there are also on-invoice discounts for purchasers based on volume starting with wholesalers to smaller distributors, then pharmacies, and large purchasers such as hospitals. Manufacturers generally offer discounts to wholesalers based on volume purchases and prompt payment. Wholesalers also offer discounts to buyers based on volume and timely payments. Rebates are paid to PBMs for preferred placement of a drug or bundle of drugs on the formulary or preferred drug list. Rebates are paid after a drug has been dispensed and periodic payments are based on the number of units dispensed. Patient cost sharing is generally based off the list price without regard to any manufacturer price concessions.[22]

The illustration in Figure 1 presents the typical supply chain flow for branded products dispensed through the retail pharmacy market and reimbursed by the PBM as a pharmacy benefit. The flow for distribution of generic drugs and payments is similar, although it lacks the influence of rebates paid by manufacturers. Pharmaceutical manufacturers noted during the focus group sessions that rebates on branded products provide cost savings of approximately 50 percent on branded products and may be as much as 80 percent on highly rebated products.

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[18] U.S. Federal Trade Commission Office of Policy Planning, *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies,* (July 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

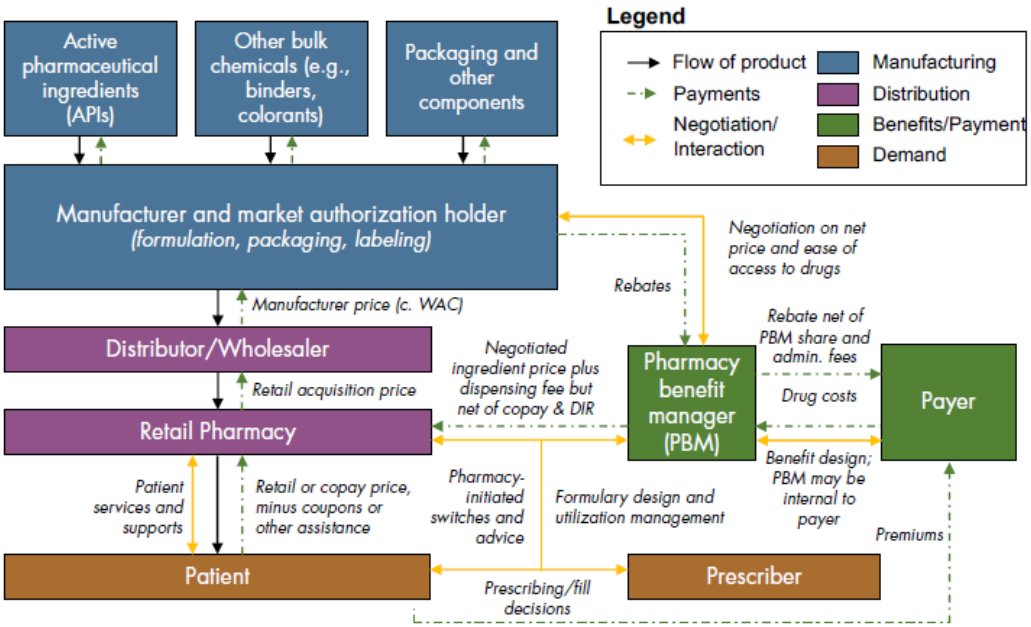
[19] U.S. Gov't Accountability Office, *Prescription Drugs the Number, Role, and Ownership of Pharmacy Services Administrative Organizations*, Government Accountability Office, (Jan. 2013), https://www.gao.gov/assets/gao-13-176.pdf.

[20] National Academy for State Health Policy, *A Glossary of All Terms Pharma,* June 15, 2018, https://nashp.org/a-glossary-of-all-terms-pharma/.

[21] Andrew W. Mulcahy & Vishnupriya Kareddy, Prescription Drug Supply Chains, Rand Corporation, (2021), https://www.rand.org/pubs/research_reports/RRA328-1.html.

[22] U.S. Senate Committee on Finance, Minority Staff, A Tangled Web: An Examination of the Drug Supply and Payment Chains (June, 2018), https://www.finance.senate.gov/imo/media/doc/A%20Tangled%20Web.pdf.

Figure 1: Typical Supply Chain for Brand-Name Drugs Dispensed Through Retail Pharmacies[23]



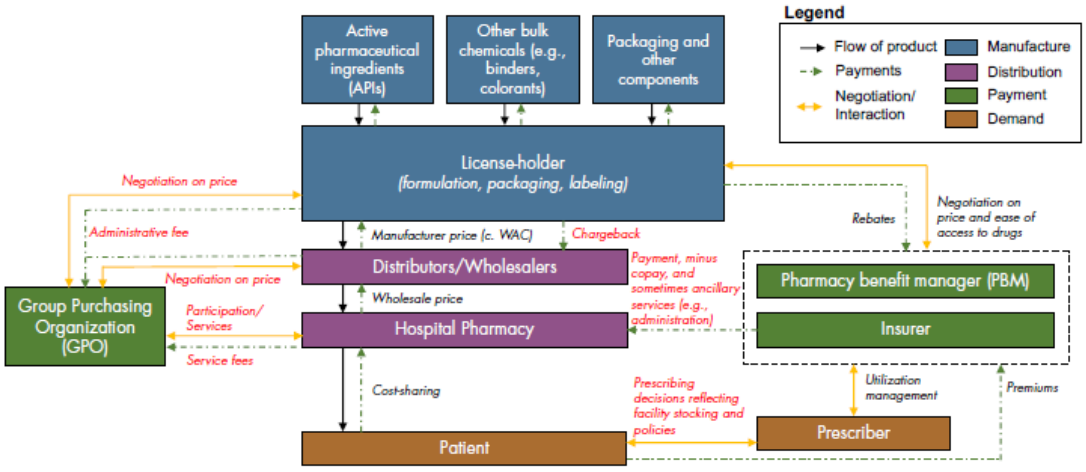
NOTES: c. = circa; DIR = direct and indirect remuneration; WAC = wholesale acquisition cost.

Distribution through hospitals and physician offices carries a similar level of complexity, as illustrated in Figure 2. Generally, prescription drugs distributed through this method are administered in settings such as hospital outpatient departments or physician offices, and often are covered through the medical benefit rather than the pharmacy benefit. White bagging (delivery by a specialty pharmacy to the provider and processed for payment by the PBM) and brown bagging (delivery by a specialty pharmacy to the patient and processed for payment by the PBM) are other mechanisms for dispensing in this setting. A more recent development is the increase in clear bagging, in which the specialty pharmacy is owned by the health system and distributes the drug to the provider for administration; claims payment is generally processed through the PBM.[24]

[23] Andrew W. Mulcahy & Vishnupriya Kareddy, Prescription Drug Supply Chains, Rand Corporation, (2021), https://www.rand.org/pubs/research_reports/RRA328-1.html.

[24] Jason Shafrin, White vs. Brown vs. Clear Bagging, Healthcare Economist (April 25, 2023), https://www.healthcare-economist.com/2023/04/25/white-vs-brown-vs-clear-bagging/.

Figure 2: Typical Supply Chain for Drugs Dispensed in Outpatient Facility Settings[25]



PDAB Landscape

As described above, states leverage a variety of public oversight laws in an attempt to control costs and increase transparency. One such method is through the creation of PDABs. PDABs are government entities charged with assessing which prescription drugs present affordability challenges to a state's health care system and to consumers. Many, but not all, PDABs are designed to identify unaffordable drugs, to help assess the causes of high costs for particular drugs, and to identify appropriate policy solutions.[26] Generally speaking, PDABs gather data regarding the cost of drugs, specifically high-cost drugs. Data is gathered from constituent groups directly, from state agencies, or from outside services and vendors. Using the pricing and cost data collected, PDABs determine whether to conduct an affordability review of the identified drugs and may subsequently set upper payment limits.

Four states, in addition to Oregon, have established PDABs with authorization to conduct affordability reviews, but unlike Oregon, also have authority to set UPLs on certain medications.[27] This authority empowers these states to establish maximum payments for specific drugs, offering a potential mechanism to contain escalating prescription drug costs and ensure affordability for patients and payers alike.

[25] Id.

[26] CO, WA, MN have statewide prescription drug UPL setting authority; MD has UPL setting authority for just state and local governments; ME and NH have unspecified cost control authority for state agencies and programs; OH, NJ only have study authority; and NY and MA have Medicaid pharmacy budget growth caps and remediation authority. OR has authority to assess affordability of certain drugs but no UPL setting authority.

[27] Additionally, thirteen states have proposed legislation to create PDABs: Arizona, Connecticut, Iowa, Kentucky, Michigan, Nebraska, Pennsylvania, South Carolina, Vermont, Virginia, West Virginia, and Wisconsin.

In addition to the states with UPL-setting authority, six states have implemented various drug affordability review initiatives, signaling a growing trend in addressing pharmaceutical pricing and accessibility at the state level.[28]

UPL States

Maryland, Minnesota, Washington, and Colorado have enacted legislation authorizing the boards to set UPLs for certain prescription drugs. While none of these states have set a UPL, the summaries below describe factors these states may consider, or have proposed to consider (i.e., Maryland), when doing so. No state's law limits what factors to consider (other than certain cost effectiveness analysis) or limits the approach to setting a UPL. The boards in three states – Maryland, Washington, and Colorado –are required to consider similar factors, such as:

- The cost of administering the drug,
- The cost of delivering the prescription drug to consumers,
- Whether the drug is included on the FDA Drug Shortage List, and
- Any other relevant administrative costs.

Additional details for each state's UPL authorization are provided below.

Maryland

The Maryland PDAB has the authority to establish payment rate limits (UPLs), but that authority only extends to drugs purchased or covered by state or local government or Medicaid.[29] The Board is required to conduct a study to determine policy options that would establish UPLs.[30] The overall UPL Action Plan has to be approved by the legislature, or the governor and the attorney general. As of this writing, the Board has identified eight prescription drugs that may be eligible for a UPL, and it voted to conduct cost reviews on six of those identified drugs.[31] The Board will then undertake a cost review to determine the affordability of the selected drugs.

At the meeting held on September 10, 2024, the Board proposed a plan of action to implement the process to set UPLs. Per the action plan, methodologies for calculating a UPL may include cost effective analysis; therapeutic class reference; indexed launch price; same molecule reference (i.e., set UPL based on costs of other products with the same active ingredients with the same indication of use);

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[28] NASHP, DRUGS TAKE DIVERSE APPROACHES TO DRUG AFFORDABILITY BOARDS (2021) https://nashp.org/states-take-diverse-approaches-to-drug-affordability-boards/. In addition to the states with UPL-setting authority, six states have implemented drug affordability initiatives through a variety of alternative methods. While these states are not authorized to establish UPL methodology, they are authorized to explore and implement other cost-saving measures for prescription drugs. In Ohio, the Board is required to issue a report making recommendations on a number of areas, such as how the state can achieve cost transparency and new payment models. In New Hampshire, the Board must establish drug spending targets and recommend strategies for public purchasers to lower costs to meet those targets. In Massachusetts and in New York, the Medicaid programs are authorized to negotiate supplemental rebates with manufacturers. In Maine, the board is authorized to determine and set spending target recommendations. Lastly, in New Jersey, the Board is authorized to identify drugs that present affordability challenges and make legislative or regulatory recommendations that would advance the state's goal of more affordable and accessible prescription drugs.

[29] Md. Laws § 21 – 2C – 13 (2024); H.B. 279, Gen. Assemb., Reg. Sess. (Md. 2023).

[30] Id.

[31] MARYLAND PRESCRIPTION DRUG AFFORDABILITY BOARD, COST REVIEW STUDY PROCESS (2024).

international reference; budget impact-based; or a blend of multiple methodologies. The draft action plan also notes additional factors to be considered when setting a UPL including any information gathered during the cost review study process or the policy review process; utilization in government-sponsored health plans; the amount of direct government purchases; net prices for government-sponsored health plans; total out-of-pocket costs for government-sponsored health plans; current coverage status of the drug in government-sponsored health plans; the number of prescriptions paid through the State Medicaid program; the number of patients for the drug helped through the State Medicaid program; the total amount paid for the drug through the State Medicaid program; any budget impact analysis; comparisons of health system costs to research and develop cost; life cycle revenue analysis; and any information that can be derived from the manipulation, aggregation, calculation, and comparison of any available information. The Board will vote on whether to adopt the plan at its next meeting.[32]

Colorado

Per statute, the Colorado PDAB may establish up to 12 payment rate limits (UPLs) each calendar year until 2025, at which point they may establish unlimited UPLs.[33] In addition to the factors listed above, the Board must consider the impact to older adults and persons with disabilities when exploring potential UPL methodologies. The Board must not include research or methods that employ dollars per quality-adjusted life year (QALY). With respect to assessing the impact of a UPL on older adults (i.e., individuals over 65), the Board will consider utilization of the drug, cost of the drug, insurance coverage type for individuals utilizing the drug, and qualitative or quantitative analyses and information submitted by individuals with lived experience or expertise of the drug's impact to older adults. Similarly, when assessing the impact to persons with disabilities, the Board may consider the therapeutic classification of the drug, including its therapeutic purpose and any conditions or diseases the drug may treat, as well as utilization of the drug, cost of the drug, insurance coverage type for individuals utilizing the drug, and qualitative or quantitative analyses and information submitted by individuals with lived experience or expertise of the drug's impact to older persons with disabilities.

Per regulation, costs to be considered include wholesale acquisition cost (WAC), average sales price (ASP), National Average Drug Acquisition Cost (NADAC), out-of-pocket spending, carrier paid amounts, public program fee schedules, net-cost estimates, Medicare maximum fair price (MFP), and cost information voluntary provided by supply chain entities. If a drug is on the FDA drug shortage list, the Board may consider availability and estimated shortage duration; shortage reason; therapeutic classification; and other related information.

The Board may set a UPL for any drug for which the Board has performed an affordability review. To determine whether a drug is unaffordable, the Board must consider the availability of therapeutic alternatives; the effect of price on consumer access; the relative financial effects on health, medical, or social services costs; patient copayment or other cost sharing of the drug; the impact on 340B safety net providers if the prescription drug is available through section 340B; input from patients and caregivers affected by the condition or disease that is treated by the prescription drug under review by the Board; and whether the pricing of the prescription drug results in or has contributed to health inequities in

[32] MARYLAND.GOV, MARYLAND PRESCRIPTION DRUG AFFORDABILITY BOARD PLAN OF ACTION FOR IMPLEMENTING THE PROCESS FOR SETTING UPPER PAYMENT LIMITS (2024) https://pdab.maryland.gov/Documents/comments/Draft%20Outline%20UPL%20Action%20Plan.2024.08.09.1700.pdf.

[33] COLO. REV. STAT. §§ 10-16-1406, 10-16-1407 (2024).

priority populations.[34] After analyzing each of these factors, the Board issues an Affordability Review Summary Report for the drug under review, which also states the Board's determination of affordability. As of the time of this writing, the Colorado PDAB has conducted affordability reviews for five drugs – Trikafta, Enbrel, Genvoya, Stelara, and Cosentyx. The Board has declared Enbrel, Stelara, and Cosentyx to be unaffordable and has voted to establish UPLs for each of the drugs.[35]

At its August meeting, the Board proposed draft revisions to its policies and procedures for conducting affordability reviews. The revisions would expand the affordability assessment to "consumers" broadly, and not just to consumers of the drug under review. Further, the revisions would require the Board to consider additional factors to determine whether a drug is deemed unaffordable. The Board will vote on whether to adopt the proposed revisions.

The Board is currently facing litigation challenging its determination that the arthritis drug, Enbrel, is unaffordable and subject to a UPL. On March 22, 2024, Amgen Inc., along with Immunex Corporation and Amgen Manufacturing, Limited, initiated legal action against Colorado's PDAB, contesting the validity of the board's decision and the regulatory framework surrounding it. The complaint filed by Amgen Inc. et al. outlines several key arguments challenging the actions of Colorado's PDAB[36]:

- **Violation of Supremacy Clause:** The complaint asserts that the Colorado law the Supremacy Clause of the US Constitution because it conflicts with federal patent law. It argues that federal patent law grants pharmaceutical manufacturers a designated period of exclusivity to market and sell their products, thereby establishing a delicate equilibrium between innovation incentives and price competition. Enbrel has had 40 years of patent and other federal market exclusivity protection.
- **Due Process Concerns:** Amgen Inc. et al. contend that Colorado's process for declaring a drug unaffordable does not ensure due process because manufacturers are not afforded a meaningful opportunity to present their case. The suit cites the absence of statutory standards to ensure a "constitutional rate of return" to a manufacturer.
- **Federal Preemption of Colorado Rate Setting Statute:** The complaint posits that Colorado's rate setting statute oversteps its bounds by attempting to dictate prices that federal healthcare programs, such as Medicare, must pay for prescription drugs on behalf of beneficiaries. This argument rests on the assertion that federal law preempts state regulation in this domain.
- **Commerce Clause Challenge:** Amgen Inc. et al. argue that Colorado's law violates the Commerce Clause of the US Constitution by extending its reach beyond state borders. This contention hinges on the allegation that the statute's broad applicability encroaches upon interstate commerce.

As of the time of this writing, no significant developments in the litigation have occurred.

[34] COLO. REV. STAT. §§ 10-16-1406(4)(a)-(j).

[35] CO PRESCRIPTION DRUG AFFORDABILITY BOARD, 2023 AFFORDABILITY REVIEW SUMMARY REPORT: ENBREL (2023). CO Prescription Drug Affordability Board, Affordability Review Summary Report: Stelara (2024). CO Prescription Drug Affordability Board, Affordability Review Summary Report: Cosentyx (2024).

[36] Complaint, Amgen Inc. et al., v. Colo. Prescription Drug Affordability Board, No. 1:24-cv-00810 (D. Colo. March 22, 2024).

Washington
Per statute, the Washington PDAB has the authority to set payment rates statewide, including for all payers and all purchasers, for certain drugs. The methodology must not include QALY considering a patient's age or severity of illness or disability to identify subpopulations for which a prescription drug would be less cost-effective. For any drug that extends life, the board's analysis of cost-effectiveness may not employ a measure or metric which assigns a reduced value to the life extension provided by a treatment based on a preexisting disability or chronic health condition of the individuals whom the treatment would benefit. Finally, the UPL must apply to all purchases by any entity and reimbursement for a claim by any carrier/health plan when dispensed or administered in the state by any means, the UPL must be reassessed annually based on current economic factors. However, carrier may disregard UPL and provide coverage if it is determined the drug should be covered based on medical necessity. The board is authorized to conduct up to 24 affordability reviews per year and to set UPLs for up to 12 drugs per year, no earlier than January 1, 2027.

Minnesota
Per statute, the Minnesota PDAB has the authority to establish statewide cost rate setting (UPL) for certain drugs provided its methodology include consideration of extraordinary supply costs, if applicable; the range of prices at which the drug is sold in the United States according to one or more pricing files (e.g., Medi-Span or FirstDatabank, or as otherwise determined by the Board); the range at which pharmacies are reimbursed in Canada; and any other relevant pricing and administrative cost information for the drug.[37] The board may not consider cost-effectiveness analyses that include the cost-per QALY or similar measure to identify subpopulations for which a treatment would be less cost-effective due to severity of illness, age, or pre-existing disability. For any treatment that extends life, if the Board uses cost-effectiveness results, it must use results that weigh the value of all additional lifetime gained equally for all patients no matter their severity of illness, age, or pre-existing disability. Finally, when setting a UPL for a drug subject to the Medicare MFP, the Board will use the MFP as the UPL. The board has begun the process of identifying eligible drugs and selecting drugs for cost review.[38]

Public Engagement Efforts

To support the work of the board and meet the requirements of SB 192 (to develop a plan for establishing upper payment limits on drugs sold in Oregon that are subject to affordability reviews), the board sought feedback from multiple constituent groups in Oregon. To fulfill its mandate to include outreach to constituent groups, the board worked with consultants Lou Savage and Myers and Stauffer LC (Myers and Stauffer) to host 23 community meetings and focus groups in April, May and June 2024. The board chair, vice chair, and consultants met with representatives from hospitals, pharmacies, insurance companies, manufacturers, pharmacy benefit managers, advocacy groups, patients and consumers. The board also hosted question and answer sessions with constituents during the July 24 board meeting.[39] In addition to the consumer and constituent group outreach, the board also offered three additional mechanisms for public engagement. Constituents wishing to provide oral comments or testimony at any scheduled PDAB meeting by submitting a public comment form no later than 24 hours before the PDAB meeting. Written comments could be submitted via a public comment form no less

[37] Publicly available Canadian prescription price/cost data comes from provincial public prescription coverage for people without drug coverage. The provinces post their drug by drug pharmacy reimbursement rates.
[38] MINN. COMMERCE DEP'T., MINNESOTA'S PRESCRIPTION DRUG AFFORDABILITY BOARD (2024).
[39] Upper payment limit study. https://dfr.oregon.gov/pdab/Pages/upper-payment-limit-study.aspx.

than 72 hours before a PDAB meeting. The same mechanisms could be used to submit oral or written comments specific to drugs under review by the board.[40]

Consumer Engagement

As previously described, the board contracted with Lou Savage, a past DCBS director of the Department of Consumer and Business Services and former Oregon insurance commissioner, to conduct in-person and online community forums across Oregon to discuss the high cost of prescription drugs and its effect on Oregonians' lives, health, and budgets. The board held events in five cities, along with two online meetings in April and May. About 156 people attended the sessions held in Portland, Lincoln City, Woodburn, Medford, Bend, and online through Zoom. For the community forums, the board selected locations around the state in venues that were centrally located and easily accessible to the public; the five in-person meetings were supplemented with two virtual meetings. The board also invited people to take a survey about medication names and costs, along with insurance coverage. Fifteen people completed the survey.

Consumers and advocates who shared their stories at the forums about their challenges with the cost of prescription drugs had a wide range of experiences; however, some common themes came through. Consumers are experiencing uncertainty, confusion, and anxiety about being able to afford and have access to the prescription drugs needed to maintain their health.

- Consumers experience uncertainty with the cost of their prescription drugs.
- Uncertainty about the ability to access prescriptions was frequently expressed.
- Consumers expressed confusion about how much they will need to pay for their prescription drugs.
- Consumers expressed anxiety about the future.

The board laid a foundation for future public input when it hosted seven community forums around the state in April and May 2024. The board can build on this foundation by engaging with the consumers throughout the year, inviting them to board meetings and informing them of the board's work. The board can also target its outreach to existing community events with high attendance. The board can plan and publicize future events well in advance and hopefully draw more people to come and share their stories about burdensome high-cost medications. The full consumer forum report can be found at https://dfr.oregon.gov/pdab/Documents/reports/PDAB-Consumer-Report-2024.pdf.

Panel Discussions

The board held seven constituent panels during their July meeting. The panels used a question-and-answer format moderated by the board chair and which served as a follow up to the focus groups and community forums the board held to collect feedback about upper payment limits. The board heard from a consumer representative and representatives from PBMs, insurance companies, manufacturers, advocacy groups, pharmacies, and hospitals/FQHCs/providers. The consumer representative spoke to the board about the personal impact of drug prices, while the remaining constituent groups were queried about topics specific to their expertise. Topics included rebate pass through to consumers, insurance benefit designs, the impact of a UPL on manufacturer pricing strategies, data and data confidentiality, patient and provider protections, reimbursement impacts, and recommendations for strategies to address drug affordability.

[40] Public comment form. https://dfr.oregon.gov/pdab/Pages/public-comment.aspx.

Constituent Group Engagement

As previously described, the board contracted with Myers and Stauffer to conduct constituent outreach on the board's behalf. The purpose of this outreach was to capture the perspectives of constituents throughout the pharmaceutical supply chain regarding a UPL in general, rather than targeting discussions around a particular model or approach. Seven constituent groups were identified for targeted outreach: 340B Covered Entities (CEs), carriers, hospitals, patient advocacy groups, pharmaceutical manufacturers, PBMs, and retail pharmacies. Myers and Stauffer then developed and administered an informal survey and facilitated two, one-hour virtual focus group meetings per constituent group, to identify perceptions regarding strengths, weaknesses, opportunities, and threats associated with a UPL methodology. The surveys included a series of questions and multiple response questions, as well as free-text questions to allow recipients to provide more detailed information on approaches, recommendations, or concerns. Focus group questions were organized around topics including the impact of drug affordability impact of a UPL, UPL methodologies, desired state of drug affordability, and recommendations or other strategies. The full report can be found at https://dfr.oregon.gov/pdab/Documents/OR-PDAB-UPL-Report-Draft-20240821.pdf.

Observations

Responses to the surveys and engagement with the focus groups found that all groups were concerned about drug affordability and the impact of drug affordability on their organizations, patients and/or members. While the constituent group discussions were not intended to assess affordability reviews or the previous work of the board, participants frequently mentioned the definition of affordability and a concern about how it should be defined. Participants also struggled to assess the impact of a UPL, indicating a need to better understand how it would be developed and implemented, and reflecting a lack of experience to draw from in other states.

Key concerns centered on revenue impact, impact to patient access, and system complexity. Regarding revenue impact, pharmacies were extremely concerned that a UPL will negatively impact already thin margins and that the savings from a UPL will come from reductions in reimbursement to providers rather than being borne throughout the supply chain. 340B covered entities, particularly Federally Qualified Health Centers (FQHCs), focused on their use of 340B savings and revenue to provide additional uncompensated services and copayment support to patients, and expressed concern that a UPL would require them to reduce or eliminate services. Patient impact concerns centered on potential manufacturer withdrawal from a market in response to a UPL, an unintended impact if manufacturers chose to reduce or eliminate patient assistance programs, and responses by PBMs or payers to shift utilization into non-UPL drugs through formulary design and benefit design changes that may lead to placing UPL drugs in a non-covered or higher copayment tier. System complexity was cited as a concern, especially related to implementation, contracting and necessary system enhancements. Participants also had questions around how the UPL was intended to be implemented for patients, payers, or providers who live or conduct business in states outside of Oregon, especially bordering states, or for costly therapies that may be administered at regional centers of excellence outside of Oregon.

Recommendations

The most frequently cited recommendations are noted in Table 1. It should be noted that there are additional recommendations that could be considered from the original Constituent Group Engagement Report presented to the board in August, 2024.[41]

[41] Draft Constituent Group Engagement Report. https://dfr.oregon.gov/pdab/Documents/OR-PDAB-UPL-Report-Draft-20240821.pdf.

Table 1: Constituent Group Recommendations

Constituent Group Recommendations								
Recommendation	**340B CEs**	**Carriers**	**Hospitals**	**Patient Advocacy Groups**	**Pharmaceutical Manufacturers**	**PBMs**	**Retail Pharmacies (Ind./GPO/PSAO)**	**Retail Pharmacies (Grocery/Chain/ Wholesalers)**
Focus UPLs on drug classes, rather than individual drugs, especially those drugs without lower cost alternatives and those representing Oregonians highest percentage of spending		✓	✓	✓			✓	
Incorporate lessons learned from other state PDABs into the board's affordability reviews and UPL planning processes		✓		✓			✓	
Ensure that the UPL is enforced across the entire supply chain (i.e., that no one pays more than the UPL), that there is transparency to the process, and that savings pass-through to patients in the form of reduced premiums or reduced drug costs is demonstrated	✓	✓		✓		✓		
Ensure transparency in affordability reviews and how UPLs are established (i.e., how the board arrives at its conclusions); establish a periodic review process for UPLs to adapt to market changes, innovation, and economic conditions, ensuring they remain relevant and effective	✓	✓		✓		✓		
Pursue comprehensive PBM reform (i.e., prohibit clawbacks, spread pricing, mandatory mail order; permit pharmacy choice, including specialty pharmacies, and a shared and common definition of specialty drugs)	✓	✓	✓	✓	✓		✓	
Eliminate the use of rebates in the various levels of the supply chain	✓		✓				✓	
Ensure that pharmacies are paid no less than the UPL and separate the dispensing fee from the cost of the drug; dispensing fees should be adequate to cover the enhanced clinical services required for specialty drugs and the cost of drugs and services in pharmacies in general	✓		✓	✓	✓		✓	

Plan for Establishing an Oregon-Specific UPL

The board has engaged in an extensive and intensive process, detailed here and in other public documents, to assess the feasibility of establishing an upper payment limit in Oregon as a method for improving drug affordability. Our discussions establish the complexity of the concept, the implementation, and regulatory considerations such an approach would warrant. As has been noted in public meetings, the establishment of a UPL would require flexibility of approach and adequate, likely lengthy, time to develop and test models, assess impacts, and implement through the rulemaking process (including public comment).

Prior to establishing UPLs, the board must first determine if a drug is unaffordable through the affordability review process. The board's enabling legislation requires the board to identify nine drugs and at least one insulin product under ORS 646A.694 that may create affordability challenges for the healthcare system or high out-of-pocket costs for patients in the state.

With UPL authority, if a drug is deemed unaffordable, the board would then consider setting a UPL on the drug or its therapeutic class. There are a variety of approaches that the board may choose to leverage; it may choose one or several of the methodologies for setting a UPL or it my subsequently identify other, unique approaches that were not contemplated at the time of this report. Upon determining a UPL approach or approaches, the board would then move through the rulemaking and public comment process to establish the upper payment limit. While the affordability review process is an important step on the path to setting UPLs, not all drugs reviewed will be considered for a UPL.

UPL Potential Methodologies

There are several approaches states may leverage when setting a UPL. The board considered a number of high-level approaches (general concepts) to setting a UPL, as well as associated methodology and implementation considerations (see Table 2 below). These are intended as a framework to drive discussion about what an Oregon-specific UPL approach might look like. Ultimately, any approach to setting a product-specific UPL could involve one or more approaches, be influenced by the type of drug (e.g., specialty, physician or self-administered, etc.), market factors (e.g., level of rebates or therapeutic competition), and other strategies that have not yet been identified. As such, this should not be considered an exhaustive list of options. Alternatively, the board may determine that a particular option presented below is no longer a viable option for consideration. There is a consensus that no single methodology will work for all drug products considered for a UPL, and that multiple approaches may be considered. The board will select the best option(s) for each drug or therapeutic class.

In addition to the potential specific approach(es) to developing a UPL, there are multiple models for implementing a UPL. A rebate model implemented at the state level would offer an opportunity for the State to leverage its buying power by consolidating utilization at the state level, including utilization for uninsured and underinsured patients that are not typically included in negotiations. This model offers the advantage of increased negotiating power, but is often hampered by opacity in the process and lack of transparency in the use of savings. Additionally, leveraging a rebate model similar to that used in the Medicare Fair Price (MFP) may not be a viable approach because it would likely place administrative burdens on providers and result in payment delays that could further threaten providers' financial viability, especially for retail pharmacies. An up-front, net cost approach would likely offer the benefits of a transparent upper cost limit throughout the supply chain and reduced administrative burden,

especially on downstream members of the supply chain such as carriers and providers. It may also provide an added benefit of visibility to patients, especially those who are uninsured or who have high coinsurance obligations. These operational level details will be determined through the rulemaking and public comment process.

Table 2: UPL Approaches (General Concepts)

UPL Approaches (General Concepts)[42]		
Concept/Source	**Description**	**Considerations**
Net Cost	Establish UPL at or near the existing average net price of the drug after any rebates or discounts negotiated between the drug manufacturer and PBM. UPL then becomes the benchmark from which patient out-of-pocket costs are calculated by payers. This is particularly useful for highly rebated drugs which are generally placed on high formulary cost share tier. Consider leveraging publicly available average sales price (ASP) data for provider administered drugs to ensure that patient out-of-pocket costs are based on reimbursement rates that reflect net price.	• Option could include use of rebates negotiated at a state-wide level • Highest potential for drugs with significant rebate opportunities • Concerns include administrative complexity and concerns around a lack of transparency • Desire to ensure distribution throughout the supply chain • Requires assurances that providers are kept whole
Reference Pricing to Existing Benchmarks	Establish UPL based on prices already negotiated or set by other entities. Reduces the administrative burden of conducting independent UPL analyses, provided that the external prices are useful comparators. Most common external references include the price of drugs negotiated by other countries, Medicare MFP, and/or price negotiated by the Department of Veterans Affairs. NASHP has published a model bill leveraging MFP as the ceiling for all purchases of a referenced drug and reimbursements for a claim for a referenced drug when the drug is dispensed, delivered, or administered to a person in the state.[43]	• Use of drug prices negotiated in other countries is an option, but is controversial and would be challenging to evaluate and implement • International reference pricing carries the risk of limiting manufacturer participation in the process • Using a U.S. published reference pricing file, such as VA federal supply schedule pricing offers the benefit of being publicly available and easily accessible and could serve as a benchmark for state-level negotiations with manufacturers • Must ensure that using VA pricing as a benchmark does not create Medicaid best price implications

[42] Program on Regulation, Therapeutics, And Law (PORTAL), Determining Upper Payment Limits: Considerations for State Prescription Drug Affordability Boards (PDABs) (2024), *available at* https://eadn-wc03-8290287.nxedge.io/wp-content/uploads/2024/04/Upper-Payment-Limit-White-Paper.pdf.

[43] NATIONAL ACADEMY FOR STATE HEALTH POLICY, AN ACT TO REDUCE PRESCRIPTION DRUG COSTS USING REFERENCE-BASED PRICING (2022), *available at* https://nashp.org/an-act-to-reduce-prescription-drug-costs-using-reference-based-pricing/.

UPL Approaches (General Concepts)[42]		
Concept/Source	**Description**	**Considerations**
Reference Pricing to Therapeutic Alternatives	Establish UPL based on the price of drugs that can be used in place of the selected drug. For drugs with multiple approved indications, the therapeutic alternatives may differ for each indication. In these instances, it may be necessary to only include alternatives that are approved for all of the same indications as the selected drug; or to set separate prices based on reference groups for each of the drug's indications. Where multiple alternatives exist, health plans and PBMs often select one or two "preferred" drugs within a class, which often have lower out-of-pocket costs for patients than non-preferred alternatives. Consider setting same UPL for all therapeutic alternatives, based on the lowest-priced drug of the group.	• Setting a UPL at a therapeutic class level increases the complexity of the analysis needed • This option could avoid some of the challenges noted by constituent groups that an unintended consequence of a UPL could be that an agent is moved to a non-preferred status to avoid the UPL • Long contracting runways with PBMs and carriers could be a barrier to implementation
Launch Price Indexing	Establish a UPL that uses the product launch price and indexes that price to the yearly or consolidated average CPI.	• Indexing the UPL to a launch price plus an appropriate annual CPI provides a straightforward option that may have reduced complexity at implementation • Concerns that increased or higher launch prices could be an unintended consequence of this approach • Changes to Medicare (new financial penalties for drug prices that increase faster than inflation) and Medicaid (price inflation penalties are uncapped and can exceed the WAC of a drug) make this option most applicable to drugs that have been on the market a long time with price increases before the change to Medicare and Medicaid rebates.
Percentage off of WAC	Establish a UPL that is a fixed percentage off of WAC. For brand drugs, the federal minimum Medicaid rebate is 23% of the AMP, which is confidential but, given the formula, is likely to be close to WAC. If a board is uncertain about the level of discounting in the market for first-in-class or other type of sole source products, but the drug is causing clear affordability challenges (e.g., clearly resultant premium increases, very high patient cost sharing, minimal manufacturer	• Offers a straightforward approach • Could leverage information available through a data call to determine a reasonable discounted WAC • Information is often hard to obtain • Inaccuracies in the data or inability to obtain the data could result in setting a WAC that is too low or too high

UPL Approaches (General Concepts)[42]		
Concept/Source	**Description**	**Considerations**
	patient assistance), this approach may be sufficient to induce payers to improve patient access.	
Payer Return on Investment (ROI)	For a drug that has been subject to valid pharmacoeconomic research on value/cost savings, establish an initial UPL with a minimal lower cost and assess health plan savings over a given period (e.g., 5 years). Limiting the period in which medical benefits and savings start to accrue is important, as multimillion dollar drugs that produce savings over a lifetime may not be affordable to the healthcare system for many years.	• Allows the board to assess the potential savings from a UPL along with a drug's positive impact on overall cost of therapy • A long period for assessment may limit the utility of the approach
Budget Impact-Based	Establish a UPL such that spending on the drug does not exceed a certain percentage of a given budget or have a disproportionate impact on a given budget. Could be accomplished by limiting the drug's contribution to increases in health insurance premiums (i.e., premium growth thresholds) or by leveraging a modified budget impact analysis to establish cost savings targets (i.e., assessment of costs only, rather than costs and health outcomes, as is done in cost-effectiveness analyses).	• Complex concept that requires more exploration • Assessment of the unintended consequences of the approach such as high launch prices
340B Program-Specific	Establish a UPL reimbursement adjustment for some or all 340B entities. The cost of drugs for 340B entities is approximately equal to the net cost after Medicaid rebate for the drug, although unlike Medicaid, it may not go below a penny. The 340B supply chain will continue to be discrete with much lower costs than even a UPL for a variety of programmatic reasons.[44] Regardless, profit on UPL drugs will be less than in the absence of a UPL.	• Requires an assessment of the cost to the 340B market • Recognition that the margins are important to Oregon covered entities since there is no state funding for non-grantee programs • Concern that this option doesn't fulfill the desire to ensure that all Oregonians benefit from a UPL

[44] For brand drugs, the Medicaid rebate and corresponding discounts available through the 340B program are based on 23 percent of the Average Manufacturer Price (AMP), which is roughly equivalent to federal WAC or, if greater, AMP minus the Best Price in the market to almost any entity *and* an inflation penalty rebate. A Consumer Price Index (CPI) penalty is added if/when the AMP of the drug in a given quarter exceeds CPI growth. In general, it is the CPI penalty that produces very low costs and very high rebates, and affects drugs that have been on the market many years. Best Price does *not* include the CPI penalty. Best Price may be much higher than the total 340B cost (i.e., federal rebate + CPI penalty). Under current law, a Board should avoid creating a UPL that creates a new Best Price, as it would likely automatically be extended to every state Medicaid program.

Analysis of Resources Needed by the PDAB to Implement UPL

Additional resources may be necessary to implement a UPL plan. The board must identify if the UPL shall be placed within the supply chain, as a pricing benchmark similar to WAC, rebate mechanisms, or another mechanism altogether that may be identified at a later time. Resources will be needed to support the development of a UPL, any costs or savings analysis that must be performed, and implementation support that may be required to support the board's ongoing work. Initial considerations are identified below and subsequent reports will likely result in additional recommendations. Resource requirements will be driven by the many options that are still under development not only for the UPL, but also by the stated desire to improve access to data, improve affordability review processes, and expand constituent group engagement.

- The board may need to utilize the services and expertise of the Office of Pharmacy Policy, Purchasing and Programs within OHA. This would be in lieu of creating a new government function or enlarging the PDAB to manage implementation. If needed, the Office could contract with wholesalers dedicated to supply UPL products into Oregon and work with manufacturers to prevent diversion.[45]
- The board may need to contract with the OHSU Center for Evidence-Based Policy to support the board's work. The Center provides assistance in areas such as strategic planning, training, and clinical and process consultation.
- Commercial products exist that can assist with determining the estimated impact and availability of rebates in the non-Medicaid space; if the board wishes to explore these options, separate funding will be required.
- If there is a desire to establish an advisory committee or council that includes representatives of the constituent community, including patients, providers, caregivers and other, the board may need additional staff to support the activities of this council. The number and type of staff would be determined after an assessment of current staff availability and workload.
- The Oregon Health Authority and plans administered by the Public Employees' Benefit Board and the Oregon Educators Benefit Board will be impacted by a statewide UPL.

Analysis of How UPL Would be Enforced[46]

A statewide UPL is generally intended to be self-enforcing. For example, suppliers, pharmacies, and hospitals have no incentive to buy a UPL product at a cost higher than the UPL given subsequent purchasers will not pay more than the UPL. Further, public and private health plans have no incentive to reimburse providers more than the UPL. The UPL amount will be widely known in the State, and consumers will be aware of what they should be charged when paying for a drug.

One potential enforcement challenge could be diversion. This has the potential to occur when a supplier buys a quantity of products subject to a UPL and then sells the product at market price into another state. In 2013, Congress passed the Drug Supply Chain Security Act (DSCSA), which establishes a track and trace system for prescription drugs to reduce diversion and counterfeiting of drugs.[47] Once the DSCSA is fully implemented, diversion will become less likely. A state may want to contract with a wholesaler dedicated to distribution of UPL products. The wholesaler can work with manufacturers on

[45] Horvath Health Policy, *Upper Payment Limit Operational Features*, March 2024.
[46] Horvath Health Policy, *Upper Payment Limits*, March 2024.
[47] U.S. FOOD AND DRUG ADMIN., DRUG SUPPLY CHAIN AND SECURITY ACT (DSCSA) https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa.

avoiding diversion. State offices that operate the federal (free) Vaccine for Children Program may also have experience to share thwarting diversion laws.[48]

Authorities Necessary for Enforcement of UPL

Leveraging UPL authority as a mechanism could improve prescription drug affordability for Oregonians; however, it also recognizes that a lengthy implementation will be required, given the effects on contractual relationships, potential procurement implications on the supply side, and a desire to ensure that implementation addresses concerns expressed by constituents. Moreover, implementation and enforcement of a UPL will require the board to conduct rulemaking through the authority granted under ORS 646A.693. The proposed list of authorities below are not considered exhaustive, and will likely require further evaluation as the board pursues its work.

- The board will require statutory authority to establish UPLs and conduct rulemaking, inclusive of a transparent public notice and comment period.
- Regulatory authority is likely required to establish an advisory council to support the board's work.
- Using a supply side or buy side approach that establishes a UPL for all transactions in the State could require regulatory authority to establish the UPL as the maximum amount to be paid throughout the supply chain.
- Regulatory authority may be required to establish a UPL at the class level, and reduce the unintended consequence of moving coverage away from a specific drug (as appropriate) in an approach that result in a situation that functions similarly to a protected class in the Medicare program.
- Regulatory authority may be required to establish an acceptable time period for implementing a UPL within systems and contracts, or to automatically apply the UPL to existing contracts without re-negotiation.
- Regulatory authority necessary to establish wholesaler relationships as needed to support the program.
- Board discussions have identified a need for improved claims data. Evaluation of recent PBM data may identify areas of improvement that will require a new or updated regulatory authority. Similarly, carrier data improvements could require updated regulatory authority to strengthen reporting requirements.
- Pharmaceutical manufacturers have indicated a willingness provide more data. Expand confidentiality protections and improve regulatory authority as needed to support these initiatives.
- Regulatory authority to establish a reporting mechanism and associated staffing to provide individuals at any level (consumers, supply chain members, etc.) with a mechanism to report noncompliance with the use of the UPL for pharmacy transactions in the state of Oregon.

Analysis of how UPLs Could be Implemented

This section will discuss the considerations for implementation for constituent groups including PEBB, OEBB, state administered health benefits, health benefit plans, and other forms of health insurance. The board's work, as described in the 2024 Annual Report, is "to consider prescription drugs that may create

[48] Horvath Health Policy, *Upper Payment Limits*, March 2024.

affordability challenges for Oregonians and the state's health care system."[49] The board work plan published on August 3, 2022, expresses an intent to study the "entire prescription drug distribution and payment system in Oregon". The discussion, which includes upper payment limits along with other options, frames the UPL as applying to "all financial transactions in this state involving a drug" and specifies that it should not "undermine the viability" of any part of the drug supply chain.[50] Throughout its deliberations, the board has consistently reiterated that an upper payment limit must not be determined to be harmful to the overall supply chain or damage an already fragile system, especially for disadvantaged populations.[51]

As described in this and other reports, the board undertook significant activities to engage constituent groups and solicit feedback on the use of a UPL, potential consequences of implementing a UPL, and alternative solutions for either developing a UPL or developing alternative or complementary strategies to improve drug affordability for all Oregonians. The board engaged consumers, pharmacy providers, PBMs, wholesalers, PSAOs and GPOs, pharmaceutical manufacturers, hospital providers, 340B covered entities, and insurance carriers licensed in the state in public comment forums. The board has also engaged with other state agencies, such as the Oregon Health Authority, to assess the impact on the state Medicaid program and on the Oregon Educators and Public Employees Benefit Boards. Each option ultimately put forth by the PDAB will be evaluated against various metrics. All metrics may not be applicable to all potential options. Generally, the approaches taken by the board will assess:

- The operational impact to constituent groups in the supply chain, including an assessment of reasonable allowances for implementation (systems, contracts and other impacts) and necessary legislative changes to ameliorate negative impacts to the greatest extent possible.
- The rulemaking necessary to ensure transparency in UPL implementation and provide financial protections for providers and consumers within the pharmaceutical supply system and ensure that providers, consumers, payers, insurance carriers, and state health authorities receive the benefit of savings generated through a UPL or other mechanisms.
- The rulemaking necessary to address the major concerns described by constituents during the forum discussions, especially:
    - Protections for the confidential and trade secret information from manufacturers, PBMs, carriers and others that is necessary to conduct affordability reviews and assess system savings and impact
    - The intersection of the use of an acquisition cost model and appropriate dispensing fee and the appropriateness of leveraging existing information from other state agencies, such as cost modeling by OEBB or PEBB or clinical reviews by the Medicaid agency, to develop Oregon-specific reimbursement models. Legislative and regulatory support will be required to appropriately gain access to the data needed to fully evaluate the impact on supply chain; for example, the impact of changes in provider reimbursement methodologies.
    - The potential to reinvest savings into the supply chain, for example, supporting changes to reimbursement models to community pharmacies or preserving access to services

[49] 2024 Report for the Oregon Legislature: Generic Drug Report Pursuant to Senate Bill 844 (2021), Oregon PDAB, https://dfr.oregon.gov/pdab/Documents/reports/PDAB-Generic-Drug-Report-2024.pdf.
[50] Oregon PDAB Agenda, Proposed Work Plan, August 3, 2022, https://dfr.oregon.gov/pdab/Documents/20220803-PDAB-document-package.pdf.
[51] Oregon PDAB Minutes, November 16, 2022 https://dfr.oregon.gov/pdab/Documents/20221116-PDAB-approved-minutes.pdf.

provided by 340B covered entities, such as federally qualified health centers, who do not otherwise receive state funding.

As the approach to the upper payment limit is defined, the board will engage the resources needed to assess the impact of any proposed upper limit on the supply chain, including gathering input from constituent groups regarding potential areas of impact. While not an exhaustive list, this could include an estimated impact on patient copayments based upon claims provided by the carriers, an impact assessment by Medicaid to ensure there is not an unanticipated impact on best price, or impact of the UPL on net costs and copayments for the benefits provided to state employees and Oregon educators.

Current Analysis of Potential Costs and Savings

The board initially aimed to analyze and model costs associated with implementing a UPL and the resulting savings across various points within the pharmaceutical supply chain. The implementation of a UPL could potentially yield savings for the State, insurers, hospitals, pharmacies, and consumers. Myers and Stauffer elected to use a net price strategy to establish a "proxy" for determining the impact of a UPL. This approach links a UPL to the net price of a drug after accounting for rebates and discounts. Many of the products selected for initial affordability were found to be highly rebateable. Since patient copayments are generally based on the total cost of a product, reducing this cost could potentially lower patients' out of pocket expenses. The complexity of the pharmaceutical supply chain, along with the intricacies of drug reimbursement, has made this analysis challenging.

Board staff provided Myers and Stauffer with data which included insurance carrier list price concessions for specific prescriptions medications, which varied by carrier and market type. The quality and completeness of this data was higher for medications that are typically dispensed by outpatient pharmacies and self-administered by the patient. Conversely, the quality and completeness of list price concession data was more limited for medications that are typically administered to the patient by a health care provider. Using the available list price concession data, it is possible to express these concessions as a percentage of the list price. For each medication, three distinct price concession percentages were selected, either based on the data received or, in cases where data was limited, based solely on historical experience. These percentages were then applied to the current list price (WAC) of each medication, resulting in three potential UPLs for each medication. These theoretical UPLs were subsequently provided to Oregon PDAB staff for use in their modeling. The PDAB staff has tasked PEBB, OEBB, and Oregon Medicaid with modeling the costs and savings associated with these theoretical UPLs using utilization data from their plans. An overview of findings are reported below; full reports are included in the appendices.

Potential savings and costs are indeterminate at this time; savings and costs will be impacted by the drugs selected for UPL and the methodologies chosen to establish the UPL.

PEBB/OEBB Analysis

On behalf of the Oregon Health Authority (OHA), Mercer Health & Benefits LLC analyzed prescription and medical drug costs, utilization, and enrollment data for PEBB and OEBB for the period of April 1, 2023, to March 31, 2024. They calculated the impact of the proposed UPL scenarios for eight selected drugs. It was expected that the reduction in in the point of sale drug prices due to UPLs would result in lowered or eliminated rebate payments. Because this was a novel proposal, the rebates retained with UPLs in place were uncertain. To account for this uncertainty, the three different UPL scenarios were modeled with no rebates (0 percent) as well as 25 percent and 50 percent of the current rebate retained, with the most conservative estimate being that rebates for the affected drugs are eliminated upon implementation. The analysis never allowed the rebate to exceed the ingredient cost for a drug/scenario combination.

Under a scenario where it is assumed there are no rebates due to an implemented UPL, the most likely outcomes range from a cost savings of $18.7 million (price reduction exceeds existing rebates) to a combined increase of $12.1 million in plan spend (where the modest price reduction is less than existing rebates). The UPL scenario prices for drugs commonly used in the medical benefit represent less of a discount from WAC than the UPL scenarios provided for drugs typically dispensed through the pharmacy benefit. As a result, there is more opportunity for savings in the pharmacy benefit than the medical benefit.

Board staff observed that the projected outcomes leading to increased program costs were based on assumptions of a modest UPL reduction from WAC and the complete elimination of all rebates. However, total loss of rebates may not be a realistic assumption. Conversely, setting a UPL close to the current net price after rebates while assuming retention of 25 to 50 percent of rebates is also unlikely. In general, if implementation a UPL results in all rebates being removed, only the more aggressive UPL scenarios result in plan savings. Board staff expect analysis of commercial plan data would have similar findings. Given the complexity of the drug supply chain, it is important to consider a range of scenarios and account for potential market shifts that could continue to offer price concessions where feasible.

Medicaid Analysis

In order to model impacts to the Oregon Medicaid program, board staff tasked OHA with modeling costs utilizing the three theoretical UPL points as above. OHA's Office of Health Analytics pulled coordinated care organization (CCO) encounter and fee-for-service (FFS) claims data for the year ending June 2024 from OHA's Decision Support and Surveillance Utilization Review System (DSSURS)/Medicaid Management Information System (MMIS) database. The Office of Actuarial and Financial Analytics (OAFA) built models for each payer and claim type, comparing actual payment levels against an estimate of payments limited by a UPL. Savings were estimated on a gross (total payments) and net (Oregon Health Plan [OHP] payments) basis. Changes to rebates were not considered in the calculation. First-dollar savings were expected to apply to OHP.

In terms of budgetary impact, the FFS costs are presumed savings, but would be offset by any reduction in pharmacy rebates. Due to timing and data constraints, OAFA did not attempt to model any rebate impacts. In assessing budgetary impact, OHA would also want to look more closely at members' category of aid to determine what proportion of the total will be state funds – 25 percent to 30 percent would be the likely proportion of state funds. In addition, there appear to be some Indian Health Care Provider claims (based on payment amounts) that should potentially be excluded from analysis. Put together, these factors suggest the $2.26 million in net FFS savings under the tightest UPL scenario might result in state budget savings of less than half a million dollars.

For CCOs, the financial impact is likely to be "absorbed" in capitation rate setting. Each year OHA tries to set capitation rates approximately 3.4 percent higher than the prior year. To the extent there are benefits or costs expansions that are not separately funded by the legislature (which happens regularly), OHA prices those into capitation rates but still fits the overall rates within the 3.4 percent budgetary increase. This process essentially subjects all other services or policy levers to a lower level of increase within the capitation rates.

In the case of the UPL application, the opposite could become true: any material expected savings to CCOs would be reflected in capitation rate development, but in absence of any direction to the contrary OHA would still target a 3.4 percent overall increase, which would leave more room for inflationary or policy increases in other areas of rate setting. However, if OHA were expecting a decrease in pharmacy rebates, the 3.4 percent target might be adjusted to offset the loss of pharmacy revenue. Therefore, unless the Legislature asks OHA to bank the savings (of which perhaps 25 percent to 30 percent would be the state's to retain), a UPL likely would not result in savings to the state but rather lead to reinvestment of the proceeds into other CCO expenditures.

For context, the CCO system is expected to incur around $6.2 billion in service costs during calendar year 2025. A savings of $56 million represents around 0.9 percent of costs, which is a significant impact in the context of rate setting. Again, offsetting for rebates foregone would reduce that potential savings/reinvestment.

Medicare Maximum Fair Price Analysis

On August 14, 2024, CMS provided an update on its progress in the Medicare Drug Pricing Negotiation Program. This program stems from the enactment of the Inflation Reduction Act of 2022, which affords CMS the "ability to directly negotiate the prices of certain high expenditure, single source drugs without generic or biosimilar competition." The CMS negotiated price for a given drug is known as the Maximum Fair Price (MFP).

As CMS continues its MFP program, Oregon's PDAB may be able to draw parallels and model similar effects if a UPL is used in the state. PDAB staff completed an analysis to examine the potential estimated savings to health plans using the recent CMS negotiated drug prices.

It is important to note this analysis was not a comprehensive comparison based on the entire Oregon pharmaceutical marketplace. The Oregon data was limited to commercial insurance carrier reporting to the Drug Price Transparency program. This only includes specific plan types (i.e., large, small and individual) while excluding groups such as Medicare, Medicaid, self-insured, PEBB, and OEBB. The analysis was only intended to model the potential savings based from the MFP negotiated pricing.

The analysis utilized carrier data and pricing from 2023 and identified potential savings per drug to be between 51 percent and 88 percent of the 2023 spend when using the MFP negotiated prices. Overall, the analysis identified approximately $37 million in savings across the 11 modeled drugs.

Future Analysis of Potential Costs and Savings

Work by Horvath Health Policy has found that upper payment limits (UPLs) will work best if the UPL applies statewide -- to all purchases, payments, billings, and reimbursements of public and private purchasers, payers, and patients. Ideally, the entire state supply of the prescription product to which a UPL is applied comes into the state at or below the UPL via wholesalers and is distributed to pharmacies, regional suppliers, and dispensing and administering providers and facilities. The product with a UPL is then available to everyone, including individuals without insurance. Under this scenario, a wholesaler negotiates with the manufacturer to buy the product at or below the UPL and the UPL replaces the wholesale acquisition cost for in-state transactions.

Once the wholesaler acquires the product, distribution (sales and acquisitions) of the product operates consistent with current practice and each participant in the supply chain realizes some margin (profit) on the product. The product (ingredient) reimbursement made by the payer is the amount of the UPL (professional fees are not part of the UPL).[52]

While Senate Bill 192 requires an analysis of the costs of implementing the plan with respect to various constituent groups, a detailed analysis is premature at this time. As specific UPL approaches are identified and finalized for specific drugs or drug classes, future analytics may be performed to estimate the cost to each of the various constituent groups. It should be noted that the discussions with specific focus groups, as detailed in other documents, provide some insight into issues or concerns that warrant additional consideration or evaluation.

Pharmacy

Assessing the impact of a UPL on pharmacies includes modeling pharmacy acquisition costs and reimbursements. With access to wholesaler drug purchasing and sales data, as well as pharmacy dispensing and reimbursement data, it would be possible to model different UPL acquisition costs and quantify savings at the pharmacy level. However, pharmacies and wholesalers are not obligated to provide

[52] Horvath Health Policy, *Upper Payment Limits*, March 2024.

drug purchase cost data. An estimate of pharmacy acquisition costs could be modeled using published resources such as the Oregon Actual Average Drug Acquisition Cost (AAAC) and the NADAC benchmarks. Additionally, the state may not have full access to non-public payer data specific to Oregon. Modeling could potentially use data from state-administered plans and summary data from state-regulated entities. Limited utilization data for government programs is publicly available, such as Medicare Part B and D summary data (which is national and not Oregon-specific) and State Drug Utilization Data (SDUD) for Medicaid programs (which can be obtained at the Oregon-specific level). However, data from cash payers may not be accessible. Pharmacy reimbursement data from PBMs and patients will be difficult to obtain and will vary by pharmacy organization. Aggregating pharmacy reimbursement data across different pharmacies would be necessary to project statewide effects. Projecting pharmacy acquisition costs in a post-UPL environment will be challenging. One approach could be to express both current pharmacy acquisition costs and pharmacy reimbursements from PBMs and patients as a percentage of WAC.

Commercial Insurance Carriers

Assessing the impact of a UPL on carriers includes an analysis to quantify total gross and net prescription drug spending and the total rebates generated. Under a UPL model, total prescription drug gross spending for a specific UPL product is expected to decrease, along with a corresponding decrease in rebates generated. The overall impact on health plans will depend on the relative change in reimbursements resulting from the UPL and any reduction in rebates after UPL implementation, which may offset each other. Pharmaceutical manufacturers would likely decrease rebates in proportion to the reduction from WAC to UPL. Consequently, once a UPL is set, current claims data could be adjusted to simultaneously decrease total payments in claims to pharmacies and reduce manufacturer rebates, resulting in a net "wash" on prescription drug net spending. Claims data for Oregon State Employee Plans (OEBB and PEBB) could serve as a representative data source for commercially insured health plans. Other data, if made available from commercial health plans with members in Oregon, could also be analyzed. However, this analysis may be limited as actual claims data and rebate data correlated with the same claims are generally considered proprietary to health plans and PBMs and may be difficult to obtain.

Patient Out Of Pocket Spending

Drug affordability often centers on patient out of pocket spending. Assessing the impact of a UPL on patients could be conducted with access to detailed carrier claims data, including pharmacy reimbursement, patient out of pocket amounts, remaining deductible, and remaining out of pocket maximum for each claim. Aggregated data will not be useful in modeling changes to patient out-of-pocket spending due to the numerous variables involved in determining where a patient stands concerning their deductible and out of pocket maximums at any given time. Existing claims data could be modeled using a UPL instead of the current total reimbursement to the pharmacy, potentially lowering patient out of pocket spending and slowing progression through deductible and out of pocket maximum phases. However, the necessary claims data to fully model the effects on patient out-of-pocket spending may not be available. Deductibles and out of pocket maximums can vary from one health plan to another, so calculations based on assumptions from one health plan should not be extrapolated to others. However, the cost to patients either at the point-of-sale or through cost-sharing or coinsurance could be expected to be reduced based on the lower list price of the drug. The availability of patient assistance programs currently provided by drug manufacturers should also be considered in an assessment of UPL impacts to patient out-of-pocket spending.

Hospitals

Assessing the impact of a UPL on inpatient and outpatient hospital charges and associated reimbursements would require various data including inpatient and outpatient standard drug charges,

mark-up methodologies, and reimbursement methodologies for hospitals. The implementation of UPLs may alter the standard charges set by hospitals to the extent that UPLs are incorporated into the mark-up methodologies for setting standard charges. Reimbursements from third parties may or may not be directly impacted by UPLs, depending on the reimbursement methodologies, which will vary by hospital, third-party payer, and whether the drug was used in an inpatient or outpatient setting.
The complexity and variability in methods for setting hospital standard charges, along with the complexity and variability in inpatient and outpatient bundled payment methodologies, present significant limitations in realistically modeling the impact of UPLs on hospital charges and associated reimbursements.

Physician Offices and Clinics

A UPL could impact both pharmacy payments and payments for drugs administered in an office setting. To model any UPL impacts in this setting, the board would require detailed purchasing data from wholesalers and reimbursement data from insurance carriers. Providers and wholesalers are not obligated to provide drug purchase cost data. An estimate of pharmacy acquisition costs could be modeled using published resources such as the Average Sales Price (ASP). Additionally, the state may not have full access to non-public payer data specific to Oregon. Data from state-administered entities (e.g., Medicaid, PEBB/OEBB) could be obtained from the state. Data from state-regulated entities may be available in summary form through data calls (e.g., commercial insurance). Limited utilization data for government programs is publicly available, such as Medicare Part B and D summary data (which is national and not Oregon-specific) and SDUD for Medicaid programs (which can be obtained at the Oregon-specific level). Data from cash payers may not be available. Provider reimbursement data from carriers and patients will be difficult to obtain and will vary by provider. Aggregating reimbursement data across different provider organizations would be necessary to project statewide effects. Projecting acquisition costs in a post-UPL environment will be challenging. One approach could be to express both current provider acquisition costs and reimbursements from carriers and patients as a percentage of WAC.

340B Covered Entities

To model the effect of a UPL on a 340B covered entity, the board would need access to 340B acquisition costs, dispensing fees, prescription drug volume and costs, as well as reimbursement data from insurers. The implementation of a UPL should not affect 340B acquisition costs for covered entities. However, a UPL would decrease total payments for drugs, thereby reducing the amount of 340B savings or revenue generated from any prescription for a drug with an applied UPL. 340B acquisition costs, contract pharmacy dispensing fee information, and utilization (by NDC) could be provided by participating covered entities. However, 340B covered entities are generally reluctant to disclose this information, and there are confidentiality concerns associated with sharing their acquisition costs.

Appendices

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Legal Considerations

Federal Patent Preemption

Importantly, upper payment limits do not regulate manufacturer list pricing. Instead, a UPL is a payment rate limit on state regulated entities that buy, sell, bill or reimburse prescription drugs. The UPL does not govern a manufacturer's price, and a manufacturer can decide to forego a state's market for the product entirely. The Medicare MFP negotiation with manufacturers is also a voluntary process and federal circuits have thus far (as of the date of this document), found that manufacturer rights are not violated by voluntary government programs. . If there is a challenge to UPLs based on patent law, a state in that case should use federal healthcare/prescription laws to show that Congress does not intend that patent rights supersede the need for affordable prescription drugs.[53] Examples of Congress' intent that patent rights should not impede access to healthcare include thirty years of the 340B program and the new Medicare MFP program.[54] Both these programs would seem to indicate that when it comes to access to pharmaceuticals and affordable healthcare, patent rights are not top of mind. In fact, the new Medicare program specifically targets drugs with exceptionally extended patents and other market protections.[55]

In *Biotechnology Industry Organization v. District of Columbia*, pharmaceutical and biotechnology trade associations, PhRMA and BIO, challenged a DC law directly prohibiting drug manufacturers from selling patented prescription drugs at excessive prices in the District as unconstitutional due to federal preemption (and Dormant Commerce Clause). The Federal Circuit agreed, reasoning that the law's exclusive focus on patented drugs would penalize high prices and restrict the full exercise of patent rights. A National Academy for State Health Policy (NASHP) white paper regarding PDABs asserts that states can mitigate preemption concerns by designing PDABs to analyze and review the affordability of both patented and non-patented products, and, if necessary, impose upper payment limits on them.[56] The judge in BIO v. DC explicitly differentiated his ruling on the DC law from potential future cases involving non-patented drugs. Consequently, a UPL law encompassing both patented and non-patented products would be legally stronger.

Dormant Commerce Clause

The Federal government, by virtue of the Constitution's Commerce Clause, regulates commerce between the states.[57] States regulate in-state commerce.[58] State regulation can have ancillary out-of-state business impacts that do not reach a threshold of regulating interstate commerce.[59] State authority to regulate commerce is not written in the Constitution but state authority to regulate commerce, or the limit of that authority, has evolved over time through court decisions and is referred to as the Dormant Commerce Clause (DCC).[60] Specifically, relying on *Dep't of Revenue of Ky. v. Davis*, manufacturers may claim that states attempts to set reimbursement rates for drugs are "designed to benefit in-state economic interest

[53] Horvath Health Policy, *How US Supreme Court Decisions on ERISA and Dormant Commerce Clause Create a Path Forward for Substantive State Healthcare Financing Reforms, Notably Prescription Drug Upper Payment Limits*, (2023).

[54] Id.

[55] Id.

[56] https://www.nashp.org/wp-content/uploads/2022/08/White-Paper_NASHP-Proposal-for-State-Based-PDABs_Sachs_042622.pdf

[57] Horvath Health Policy, State Prescription Drug Affordability Board and the Dormant Commerce Clause (DCC), April 2023.

[58] Id.

[59] Id.

[60] Id.

by burdening out-of-state competitors" therefore violating the DCC.[61] To further support their claim, manufacturers may point to the recent case, *Association for Accessible Medicines v. Frosh*, in which the court struck down a Maryland law that prohibited "price gouging in the sale of an essential off-patent generic drug" on the grounds that it "directly regulates transactions that take place outside of Maryland."[62] In the NASHP white paper cited above, the authors argue that there are at least two reasons that manufacturers' DCC claims are likely to fail. First, PDABs can choose to limit their UPLs to sales made or products distributed within the state thus limiting DCC concerns. Second, the Association for Accessible Medicines decision applied a more restrictive reading of the DCC than previous courts and therefore is arguably a departure from existing DCC precedent. Also, the branded drug industry operates differently than the multi-manufacturer generic drug product industry and those supply chain distribution differences are substantial. Remediation in the *Frosh* and other price gouging legislation allows a state to require a roll back of prices for multi-source generic product sold in the state at the unacceptable price as one example of a Commerce Clause question.

Medicaid "Best Price"

The Medicaid Drug Rebate Program (MDRP), authorized by Section 1927 of the Social Security Act, requires that drug manufacturers enter into a rebate agreement with the Department of Health and Human Services in exchange for state Medicaid coverage of most of the manufacturer's drugs. The rebate formula is set in statute and is designed to ensure that the Medicaid program receives the "best price" available in the marketplace (i.e., the lowest price offered to any U.S. purchaser or payer during a rebate period) or if greater, a flat rebate percentage as specified in federal law. In effect, if a UPL is lower than the deepest price concession in the market, this would create a new national best price available to all Medicaid programs. A UPL that would create a new national Medicaid best price would likely be challenged as a dormant commerce clause violation with implications for the UPL program. A State would presumably obviate a UPL that created this situation.

ERISA Preemption

ERISA is a federal law that sets minimum standards for private, employer-sponsored retirement and health plans. ERISA preempts "any and all state laws" to the extent that they "relate to" employee benefit plans.[63] Whether state laws are preempted by ERISA has been debated by federal courts through the years, leading to a complex web of competing judicial decisions surrounding the issue.

The question of whether a UPL set by a state PDAB is preempted by ERISA has not yet been considered by the courts. Perhaps the most instructional case for how courts may rule on an ERISA challenge to a UPL methodology is *Rutledge v. Pharmaceutical Case Management Association*. In *Rutledge*, the Court held that "state rate regulations that merely increase costs or alter incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage are not preempted by ERISA."[64] As long as the state law does not bind plan administrators to any particular choice, a state law will not be preempted by ERISA. Establishing a UPL methodology is a rate setting measure, and the court in *Rutledge* held that state rate setting is not preempted by ERISA.

[61] *Dep't of Revenue of Ky. v. Davis,* 553 U.S. 328, 338 (2008) (quoting New Energy Co. of Ind. v. Limbach, 486 U.S. 269, 273-274, (1988)).

[62] *Association for Accessible Medicines v. Frosh* 887 F.3d 664 (4th Cir. 2018).

[63] 29 U.S.C. § 1001 Et. Seq.

[64] *Rutledge v. Pharmaceutical Case Management Association*, 141 S.Ct. 474 (2020).

On the other hand, a Supreme Court case from 2016, *Gobeille v. Liberty Mutual,* upheld the ERISA plan objection to reporting data to the Vermont All Payer Claims Database.[65] The Court found that the administrative burden of complying with various state claims payment, enrollee data, and other plan data reporting laws affected the heart of plan administration, and, therefore, the state law was preempted by ERISA.[66] Unlike in *Gobeille*, where the state law affecting reporting was struck down because it interfered with nationally uniform plan administration, establishing a UPL in Oregon likely will not interfere with the administration of ERISA plans. A UPL is a requirement to buy and bill at the UPL. The ERISA plan benefits and basic administrative functions are not affected.[67] Implementing a UPL using rebates to plans may be complicated by ERISA preemption.

Medicare Preemption

Recent case law has expanded interpretations of federal preemption of state laws that might affect Medicare Parts C and D plans. The preemption is arguably broader than ERISA. Regardless of preemption, a UPL is designed for the passive participation of ERISA and Medicare plans as they are billed at the UPL by pharmacies, clinics, and other providers. Presumably the UPL is less than the prevailing market rate that would otherwise be used in provider billing, so ERISA and Medicare plans have no incentive to reimburse higher, but they could. However, because the preemption is broad and can be litigated by any constituent group, such as drug manufacturers, it is best to specify in law that a UPL cannot be enforced in Medicare Part D. Medicare preemption may complicate implementing a UPL via rebates.

[65] Horvath Health Policy, *How US Supreme Court Decisions on ERISA and Dormant Commerce Clause Create a Path Forward for Substantive State Healthcare Financing Reforms, Notably Prescription Drug Upper Payment Limits*, (2023). Gobeille v. Liberty Mut. Ins. Co., 577 U.S. 312 (2016).

[66] Id.

[67] Horvath Health Policy, *How US Supreme Court Decisions on ERISA and Dormant Commerce Clause Create a Path Forward for Substantive State Healthcare Financing Reforms, Notably Prescription Drug Upper Payment Limits*, (2023).

Upper Payment Limit Operational Features, Horvath Health Policy

In General

Upper payment limits (UPLs) will work best if the UPL applies statewide -- to all purchases, payments, billings, and reimbursements of public and private purchasers, payers, and patients. Ideally, the entire state supply of the UPL prescription product comes into the state at or below the UPL via wholesalers and is distributed to pharmacies, regional suppliers, and dispensing and administering providers and facilities. The UPL product is then available to everyone, including people without insurance. The wholesaler negotiates with the manufacturer to buy the product at or below the UPL.

Once the wholesaler acquires the product, distribution (sales and acquisitions) of the product operate the same way as they always have and the supply chain makes some margin (profit) on the product along the way. The acquisition cost to the pharmacy/other providers should not be more than payer reimbursement formulas. In a statewide scenario, the payer product reimbursement is the UPL (professional fees are not part of the UPL).

In setting the UPL for a drug product of concern, the Board will take into consideration whether there are exceptional handling or storage requirements for the drug of concern, among many other considerations.

Oregon may want to consider utilizing the services and expertise of the Office of Pharmacy Policy, Purchasing and Programs within the Oregon Health Authority. This would be in lieu of creating a new government function or enlarging the PDAB to manage implementation. If needed, the Office could contract with wholesalers dedicated to supply UPL products into Oregon and work with manufacturers to prevent diversion.

Enforcement

A Statewide UPL is generally self-enforcing. Suppliers, pharmacies, hospitals have no incentive to buy a UPL product at cost higher than the UPL because subsequent purchasers will not pay more than the UPL and public and private health plans have no incentive to reimburse providers more than the UPL. The UPL amount will be widely known in the State; consumers will be aware of what they should be charged when paying for a drug. The potential enforcement challenge could be diversion: a supplier might buy a quantity of UPL product and then sell the product at market price into another state. This will be easy to track once the federal 'track and trace' program is fully implemented and will diminish the feasibility of diversion. The Oregon Attorney General's office would have general authority to pursue violations of laws.

Self-Funded Employer Plans and Medicare

Because providers and suppliers buy and bill at no more than the UPL, ERISA plans and Medicare will be billed at the UPL, like all other insurers/payers in the State. Oregon cannot enforce a UPL against Medicare but there is no obvious reason for Medicare to reimburse more than billed.

2024

Upper Payment Limits

PROCESS AND METHODS FOR IDENTIFYING COST REVIEW ELIGIBLE DRUGS, COST REVIEW DRUGS, AND DRUGS THAT DO/WILL CREATE

AFFORDABILITY CHALLENGES

JANE HORVATH

HORVATH HEALTH POLICY, | Innovations in Healthcare Financing

Upper Payment Limits

Upper Payment Limits

Executive Summary

The purpose of this document is to support the members and staff of Prescription Drug Affordability Boards, as well as stakeholders involved in the work of the boards. This is difficult work and board members may be helped by having a background document about affordability and upper payment limits. While there is an expectation external to the boards that they can act quickly, this is difficult to do while also being deliberative, particularly concerning rules and guidance about how a board will operate and what its drug affordability process will entail.

The document opens with a thumbnail description of how an upper payment limit (UPL) could operate in a state. A key point is that it replaces the wholesale acquisition cost (federally defined WAC) in purchases, payments, billing and reimbursement. The base of a transaction can be less than the UPL, but not more.

UPLs should be designed to achieve large goals – improved patient access to a product, improved manufacturer access to the market/patient, and improved affordability for the healthcare system. With this perspective means a board should take a broad view of affordability, with a focus on costs and spending – including what manufacturers spend in patient assistance and rebates, what health plans spend, and what it costs a patient under the design of health plan formularies across the state. This information generally sets the parameters of the current product market and literally determines affordability for an insured patient.

There are potentially many approaches to setting a UPL, some more complex than others. Several approaches are discussed in this paper. A key point is that a board may want to specify several different approaches it would use as appropriate but maintain flexibility to use additional approaches when needed. A board will almost certainly want more than one approach to setting a UPL and rules/guidance should reflect this.

Boards are generally required to identify a set of drugs that meet certain criteria and then to choose from that group, one or more drugs that should undergo an actual cost review to determine if the drug is a financial stressor on patients or the healthcare system. The process can be resource intensive but it would be good for a board to have metrics and criteria for moving from one stage to the next.

The topics presented here provide a basic understanding about how a statewide UPL could function and operational suggestions that can spur additional, indeed better, ideas. The intent is to facilitate a board's discussion and deliberation about how it wants to proceed and what it wants to accomplish.

UPL Brief Overview

Operation in brief

Upper payment limits (UPLs) will work best if the UPL applies statewide -- to all purchases, payments, billings, and reimbursements of public and private purchasers, payers, and patients. Ideally, the entire state supply of the UPL prescription product comes into the state at or below the UPL via wholesalers and is distributed to pharmacies, regional suppliers, and dispensing and administering providers and facilities. The UPL product is then available to everyone, including people without insurance. The wholesaler negotiates with the manufacturer to buy the product at or below the UPL.
The UPL replaces the wholesale acquisition cost for in-state transactions.

Once the wholesaler acquires the product, distribution (sales and acquisitions) of the product operates the same way as it always has and the supply chain makes some margin (profit) on the product along the way. The payer product reimbursement is the UPL (professional fees are not part of the UPL).

In setting the UPL for a drug product of concern, a PDAB will take into consideration whether there are exceptional handling or storage requirements for the drug of concern, among many other considerations.

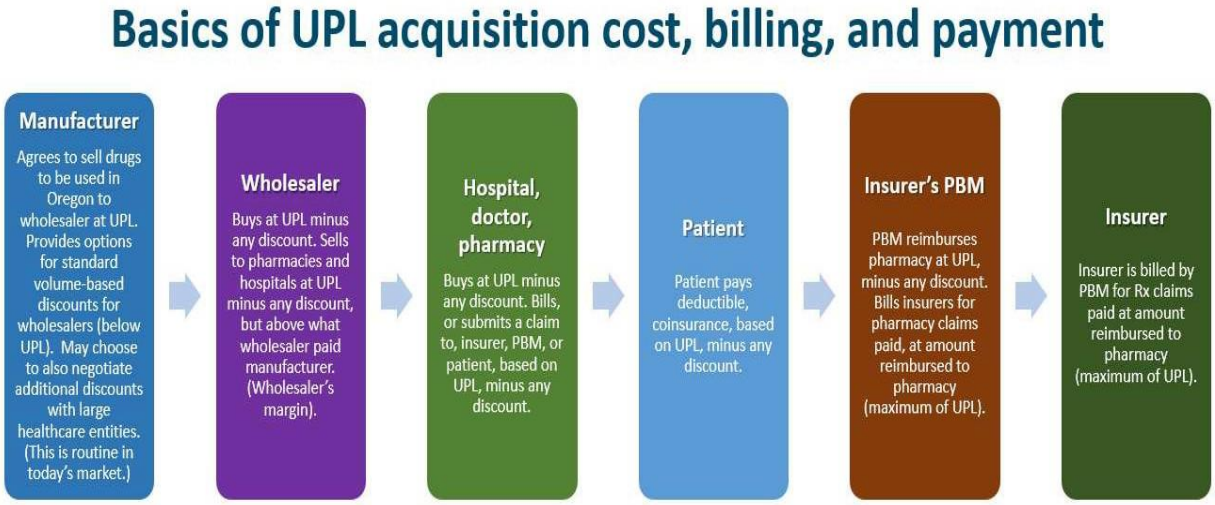
Enforcement

A Statewide UPL is generally self-enforcing. Suppliers, pharmacies, hospitals have no incentive to buy a UPL product at a cost higher than the UPL because subsequent purchasers will not pay more than the UPL; public and private health plans have no incentive to reimburse providers more than the UPL. The UPL amount will be widely known in the state; consumers will be aware of what they should be charged when paying for a drug. The potential enforcement challenge could be diversion: a supplier might buy a quantity of UPL product and then sell the product at market price into another state. Once the federal 'track and trace' program is fully implemented, diversion will become less likely. A state may want to contract with a wholesaler dedicated to distribution of UPL products. The wholesaler can work with manufacturers on avoiding diversion. State offices that operate the federal (free) Vaccine for Children Program may also have experience to share thwarting diversion. The Attorney General's office would have general authority to pursue violations of laws.

Self-Funded Employer Plans and Medicare

Because providers and suppliers buy and bill at no more than the UPL, ERISA plans and Medicare will be billed at the UPL, like all other insurers/payers in the State. Enrollees will pay deductible and coinsurance based on the UPL (unless the health plan wants an enrollee to pay less than the UPL). The UPL is the pharmacy acquisition cost.

A state cannot require that Medicare B, C, or D use the UPL for product reimbursement because of broad Medicare preemption of state law; but there is no obvious reason for Medicare (including Medicare plans) to reimburse more than billed. *PDAB regulations should specify that a UPL cannot be enforced with regard to Medicare Parts B, C, and D reimbursements of UPL drugs to eliminate the possibility of a lawsuit by manufacturers or others.* ERISA plans are in the rate setting mix like other health plans and direct purchasers. It is very important that public, commercial and employer plans work with the PDAB to ensure that the UPL is sound – at or below the current insurer net cost for the product. Additionally, consumers will want to see the benefit of a UPL, even when UPL products are subject to copays (in contrast to coinsurance). Health plans should work with the Board on this aspect of UPL as well.



Note: UPL replaces WAC, AWP, AAC, EAC etc. UPL is the metric for all financial transactions for ingredient cost. Like existing metrics, there will be 'UPL minus' ingredient costs in the supply chain.

Dispensing or administration fees, independent of ingredient cost, will still be charged by pharmacies or the health care provider administering the drug to the patient.

Upper Payment Limits: General Considerations and Features

What UPLs Can Achieve

Upper Payment Limits (UPLs) are a form of healthcare rate setting implemented by a state prescription drug affordability board (PDAB) or similar body. A UPL establishes a maximum amount that suppliers, patients, providers, and health plans will pay and/or bill for certain prescription drugs. UPLs aggregate an otherwise highly fractured market for a drug product to arrive at a more affordable cost for more parts of the healthcare system/market. UPLs are one of the very few ways a state can work to lower the cost of prescription drugs for consumers at the point of service and start to broadly address the market-wide dysfunction that has led to ever increasing prescription drug costs.

UPLs should improve market function for prescription products that have a UPL, with a particular focus on consumer affordability. The actual dollar amount of a UPL should strive to achieve one or more of several goals:

- Improve patient access to the product
    - Pharmacy 'drop' rates should improve, patient adherence should improve, utilization management should be for clinical purposes only and no longer be purposed for cost containment.
- Improve manufacturer product access to the state market
    - Cost-based utilization management tools should be minimized, greater adherence for those already on treatment, and more sales for those who have not been able to afford treatment.
- Reduce health plan costs for the product
    - Health plan product reimbursement to pharmacies and providers will be reduced commensurate with the lower product costs for providers and pharmacies.
- Reduce overall market dysfunction
    - To the extent that pharmacy benefit managers and larger institutional providers distort the market and drive-up consumer, health plan, and manufacturer costs, the UPL should level-set the market for an individual drug.
    - The UPL becomes the list price (the wholesale acquisition cost, WAC) and becomes the pharmacy and provider actual acquisition cost for purposes of reimbursement.
    - Market participants can buy and bill for less than the UPL, but not more than the UPL.
    - Market competition continues but is reset to the UPL as the starting point. Even if some competitive opacity remains in the market after a UPL is created, the consumer is protected since the UPL is a public number and is the basis for all consumer costs.

Upper Payment Limits

Why Statewide UPLs are Optimal

Upper payment limits (UPLs) will work best if the UPL applies statewide -- to all purchases, payments, billings, and reimbursements.[1] Ideally, the entire state supply of the UPL prescription product comes into the state at or below the UPL via wholesalers and is distributed to pharmacies, regional suppliers, and dispensing and administering providers and facilities. The UPL product is then available to everyone, including people without insurance. The wholesaler negotiates with the manufacturer to buy the product at or below the UPL. The UPL travels with the product through the supply chain to the point of service.

The 340B supply channel or channels for participating 340B entities will continue unchanged since 340B is a federal program.[2] Other manufacturer price concessions executed via rebates or fulfilled by wholesalers as well as the chargeback process will continue without any operational change required.

Once the wholesaler acquires the product, distribution (sales and acquisitions) of the product operates the same way as it always has; the supply chain makes some margin (profit) on the product along the way. The acquisition cost to the dispensing pharmacy/other providers should not be more than payor reimbursement formulas – acquisition and reimbursement should be no more than the UPL. In a statewide scenario, the payor product reimbursement is the UPL (professional fees are not part of the UPL).

The UPL product is available at pharmacies (and provider offices depending on the product). Consumers are charged insurance cost-sharing, including the deductible, based on the UPL. The pharmacy bills the insurer based on the UPL, and the insurer reimburses the pharmacy based on the UPL. Uninsured people pay based on the UPL. Insurers should be encouraged or required to move a UPL drug with a high cost-share to a lower cost share tier. States can also require insurers to report on how they used UPL savings to reduce consumer costs (which will be done in Colorado and several other states as a matter of law).

In setting the UPL for a drug product of concern, a prescription drug affordability board or similar body will take into consideration whether there are exceptional handling or storage requirements for the drug of concern, among many other considerations.

A state could contract with wholesaler(s) (if needed) as the dedicated supplier(s) of UPL products into the state. That dedicated wholesaler could assist in making the UPL well-known and well-understood by the providers and pharmacies and could work with manufacturers and state officials to prevent diversion out of state. Wholesalers have operational expertise that

[1] Regulated pharmacy benefit managers of commercial and employer plans would comply. Note that Medicare cannot be required to reimburse at the UPL because of broad federal preemption but state licensed entities can be required to bill all insurers at the UPL. Why Medicare would pay more than billed is not clear, but it could do so.

[2] The 340B price will almost always be less than the UPL a board could set since 340B includes the very best price in the market as well as all the add-on penalty rebates that apply when a manufacturer increases price faster than the CPI.

could be especially helpful to a board, government payors and purchasers, and the private sector as UPLs are implemented.

Different Aspects of Affordability

Costs May Be More Important Than Most Market Prices

Boards will approach their work in different ways, but it may save time if a board thinks less about all the different market prices and provider product reimbursement rates and instead thoroughly considers costs (or spending), net costs/net spending. Patient access is a function of costs and or spending such as:

- Patient costs (and access to the product);
- Employer and commercial health plan spending on a product (and how patient access may be impeded by formulary placement);
- Government program costs; and
- Manufacturer costs to gain product access to the market.

Of course, there are some key market prices/reimbursement rates essential to the work of a board – the manufacturers list price (wholesale acquisition cost), the manufacturer's so-called 'best price' in the market, the Medicare Part B Average Sales Price and soon, the Medicare Maximum Fair price. Other provider reimbursement rates used by different payors may be important in determining a specific UPL.

A UPL should not be greater than a Medicare Average Sales Price (ASP). A UPL should not be lower than the best price in the market because it could trigger a federal requirement that a manufacturer's best market price must be given to all state Medicaid programs and the federal 340B program. Although the Medicare Maximum Fair Price (MFP) will not be in the market until 2026, the UPL may have to be the same as the MFP for operational reasons and possibly for reasons of federal statute. But in the main, affordability revolves around costs in the market, rather than all the various insurer and public program reimbursement rates.

Manufacturer 'Willingness to Discount'

For many products, a manufacturer contributes large sums of money to ensure market access to, and utilization of, a high-cost product including:

- ten of thousands of dollars per patient per year in direct cost-sharing assistance for some products amounting to millions of dollars nationally per year; and
- millions of dollars in rebates to PBM/insurers/employers in-state and nationally.

A board may want to think about these substantial sums as a manufacturer's willingness to discount to gain market access.[3]
A board may also want to think about manufacturer patient assistance as a clear indication the manufacturer understands that the drug creates substantial affordability challenges for the healthcare financing system and then, in turn, problems for individual patients.[4]

Insurers and their PBM vendors use formulary design to bring manufacturers to the table to negotiate rebates. Placement of a drug on a high cost-share tier which financially burdens a patient is, by design, anathema to manufacturers since high cost-sharing reduces patient access to the product. In order to improve patient access, a manufacturer will provide rebates to the plan/PBM if the drug is moved to a lower patient cost sharing tier.

Manufacturers may provide hefty rebates but because the drug is extremely expensive, patients may continue to shoulder a high cost sharing burden. Health plans may further impede manufacturer access to the market with utilization management tools such as step therapy, quantity limits, and prior approval which burden patients and providers.

Health Plan 'Willingness to Pay'

The health plan/PBM places the drug on a formulary based in its willingness to pay.[5]
Willingness to pay is primarily based on cost. However, willingness to pay can be affected by the clinical safety or (in)effectiveness of a product relative to other therapeutic options, or even if there are no therapeutic alternatives.

Health plan willingness to pay for a particular treatment is an evaluation of the merits and costs of a product as well as the need to finance all appropriate health care treatments for all enrollees – pharmaceutical and otherwise. (Importantly, the PBM does not finance healthcare but is merely an administrator of the pharmacy benefit and is fully reimbursed for its services. PBMs do not have to balance competing costs pressures because PBMs are not at financial risk, quite unlike their health plan clients.)

For any particular drug product under discussion, it is important for a board to know the tier a drug product is on and the cost share required of that tier. This information is arguably more important than simply knowing the average plan per person spend, or the 'average patient' out of pocket spend which are only secondarily informative for policy development. It is more

[3] The amount of money a manufacturer may spend to gain market access begs the question of why the manufacturer does not simply lower the product price but the answer to that question is beyond the scope of this paper.

[4] A board should also note that rebates are in the market and are included in a manufacturer's calculation of Medicaid best price although rebates to insurers/PBMs are not included in the manufacturer calculation of the Medicaid average manufacturer price. Patient cost sharing assistance is not, by regulation and law, included in manufacturer calculation of best price or average manufacturer price.

[5] Willingness to pay as used here is different than the willingness to pay concept as used in cost effectiveness analysis.

useful to know the average plan patient out pocket cost requirement among health plans rather than simply the average patient's total annual spending.

A board can take the health plan tier information, and create, for any drug,

- the range of tier placement across health plans,
- the median tier placement across health plans,
- the range, mean, and median tier copay amount among health plans,
- the range, mean, and median coinsurance percentage among health plans,
- the number of plans that apply utilization management to a product – step therapy or prior authorization in particular,
- the number of plans that do not cover the product.

Knowing the WAC of a drug and the monthly cost makes it easy for a board and the public to understand patient costs in the context of employer and health plan formulary design.

Individual plan information can be kept confidential, although none of this should be considered a trade secret since patients live with these plan designs and Medicare Part D, Marketplace plans, and typically Medicaid plans make their formularies publicly available.

People without insurance have much greater problems affording medicine. A board may want to try to develop additional strategies beyond UPLs for people without insurance, particularly if a state has a high rate of people without coverage.

Patient Ability to Pay

In addition to understanding employer/health plan cost sharing requirements, a board should consider assessing if patients are challenged paying for the drug. Physicians may have a sense of how drug costs affect patient ability to adhere to treatment. Pharmacists may also have a sense of patient ability to adhere to treatment -- particularly failure to pick up filled prescriptions or hearing patient concerns when a prescription is picked up. Medical specialty societies and pharmacist associations may be able to reach out to their members on behalf of a board to obtain information about provider/patient experience with affordability.

Independent Pharmacist Ability to Stock and Dispense

Another factor that can affect patient affordability and even patient access is whether independent community pharmacists (as distinct from national chain pharmacies) find it difficult to stock a product because of cost and if they are under-reimbursed for the product, which only compounds the financial stress. Independent pharmacists, as a group, are consistently under-reimbursed by vertically integrated PBM/insurer/retail pharmacy/specialty pharmacy corporations whose product reimbursement strategies are designed to limit profits of their

competitor retail chains. If an independent pharmacy must lose money to dispense a high-cost product, they likely cannot stock it. There is a cascade effect which harms patients and sometimes entire communities. A board may want to see if the state independent pharmacy association can collect independent pharmacy data on product reimbursement, product cost, and patient access.

There are a variety of data points that can help a board understand the extent to which there is an affordability challenge in the state and calibrate the magnitude of that challenge. Some of this data could be useful to establishing a UPL if it is determined there is an affordability challenge. In most cases these data will be more useful for an affordability assessment than routinely knowing the provider reimbursement rates of different health plans and government programs.

Determining an Upper Payment Limit

Assessing Areas of Market Dysfunction

If a board determines that a drug product is creating or will create a healthcare financing affordability challenge, it may decide that an upper payment limit can assist to diminish the challenge. There are a number of market problems in addition to drug price which affect patient costs and affordability. Understanding if there is market dysfunction and the nature of the dysfunction is important to deciding whether a UPL is a good response, and how that UPL might best be applied to address multiple aspects of the affordability challenge.

What is the level of market dysfunction concerning the product?

- Manufacturer spending for market access
    - Is a product highly rebated yet patient cost share is also uncomfortably high?
    - Is the manufacturer providing both rebates and patient cost sharing assistance?
    - Are health plans allowing patient assistance to count toward a patient's out of pocket annual cap?
    - Are products with significant on-invoice purchase discounts (such as 340B discounts) being used to ease patient and health plan affordability concerns?
- Are insurers/PBMs together with a manufacturer impeding patient access to generics or more likely, biosimilars?
- Is it difficult to obtain insurer approval to prescribe the particular drug where the difficulty is due to cost, not clinical issues?
- Can independent pharmacies (or providers in the case of physician-administered drugs) afford to stock the drug?
- If one would expect competition among therapeutic alternates (including biosimilars), is there market competition?
- What is the effect on insurer costs of any new state or federal laws limiting patient cost sharing or total out pocket spending?

- Can a UPL help employers and health plans manage costs in the context of state or federal laws that require limits on patient out of pocket costs?[6]
- Can a UPL stymie manufacturer ability to raise costs once patient out of pocket costs are capped?

Existing Market Discounts Applied to UPL

A board could seek to understand the level of manufacturer price concessions/rebates available to health plans in-state as well as any price concessions/discounts available to in-state direct purchasers and apply those price concessions to create the UPL. (WAC minus average/largest/median price concession =UPL). These discounts are one component of a manufacturer's willingness to discount.

A board should try to avoid a UPL that increases net costs for plans. To the extent the UPL is not as low as the lowest net cost in the state, that payor or purchaser still has the same tools and relative market leverage available to extract additional price concessions from a manufacturer to maintain the same net cost.

Manufacturer Cost Sharing Assistance Applied to UPL

A board could consider applying the patient assistance amount to the UPL. (WAC minus patient assistance amount=UPL).[7] Cost sharing assistance is another component of a manufacturer's willingness to discount. This approach would use money the manufacturer already has put on the table so to speak.

A board should not apply the manufacturer's per patient maximum cost share assistance directly to the UPL. Medicare and Medicaid beneficiaries who use the product do not access individual manufacturer cash patient assistance.[8] Therefore, manufacturer cost sharing assistance applied to a UPL has to be calibrated to not overstate the amount of cash assistance present in the state.

Manufacturer patient assistance spending applied to a UPL must be further calibrated so that it does not create a new Medicaid best price, which might then require the manufacturer to give the equivalent of a state's UPL to all state Medicaid programs.[9] Manufacturer spending on

[6] For instance, the new Medicare law that will limit total Medicare Part D out of pocket spending to $2000 may affect employers that run their own Part D retiree plan. A drug that is otherwise creating an affordability challenge for patients may then create more serious financial challenge for the employer once there is a $2000 total out of pocket patient spending limit.

[7] A UPL cannot be greater than the *best price concession* already in the market because the manufacturer must then, by law, provide that best price to all Medicaid programs. That would likely trigger a claim that the UPL violates the dormant commerce clause.

[8] Medicare and Medicaid enrollees who cannot afford the product may still get manufacturer assistance in the form of 'free goods.' Free goods are completely different than cash assistance which is design to improve revenue generating market access. Free goods do not create market distortions the way cash assistance for insured patients creates distortions.

[9] See appendix for further discussion of UPLs and Medicaid best price.

patient assistance is not considered a price concession that is included in calculating the manufacturer's best price in the market. Making an estimate of all patient assistance in the state market and applying that, without modification, to the UPL could potentially create a new best price and potentially invite a legal challenge based on existing dormant Commerce Clause caselaw.

A board should have the agreement of as many commercial and employer health plans as possible to modify their formularies to reflect the lower product cost (the UPL) pharmacies and other providers will charge. Plans should be asked to reconsider any utilization management tools applied to the drug product if those policies address cost rather than clinical issues.

Ensuring that health plan formularies reflect the existence of a UPL is important for consumers and important in the event of any industry legal challenge. If commercial plans and employer plans cannot be encouraged to do this, then laws of many states that license and regulate PBMs may be able to compel PBMs to adjust formulary tiering. Medicare Part D plans may not be compelled to adjust tiering owing to Medicare Part D preemption of state laws that is broader than current ERISA preemption case law. Part D beneficiaries, however, can vote with their feet annually to move to a plan where the coinsurance percentage or the copay amount on a UPL drug is lowest.

Class-Wide UPLs to Improve Market Function

For crowded therapeutic categories (such as anti-diabetics for purposes of discussion) and classes (insulins/long-acting insulins for purposes of discussion) it might be appropriate to consider setting a UPL that applies to an entire class, such as long-acting insulins (again as an example for purposes of discussion).[10] If products in the class are priced similarly and have competitive rebate price concessions (as did insulins), then a UPL on the class might be an approach worth consideration. Setting a UPL for all long-acting insulins avoids the problem of addressing the cost of one product when all therapeutic competitors behave the same way in the market. Even though one would expect setting a UPL for one product would have a sentinel effect on the in-state cost of all products in a class, the class-wide approach does not single out one competitor.

Class-wide UPLs could thwart attempts by PBMs to prefer a higher cost, non-UPL therapeutic alternative product with higher rebates. Such a move by a PBM would increase PBM revenue relative to the UPL product, which would undermine the basic goal of the UPL and occur at the expense of the consumer. If the UPL applies to all products in the class, the PBM cannot select

[10] Insulin affordability has been addressed through federal Medicare policy and the laws of many states, but it is a good example for purposes of this paper for how to think about a class wide UPL since many people are familiar with the cost dynamics of this class, as well as the state/federal/manufacturer efforts to increase affordability which may make further board action on this class unnecessary, but still a good hypothetical of class-wide UPL use.

the non-UPL product for the preferred tier and the patient is protected regardless of what price concessions a PBM negotiates with the manufacturer of the preferred product.

Additionally, a class wide UPL could complicate an effort by any one manufacturer to initiate a product boycott. If all manufacturers boycott, there might be an anti-trust issue. If some manufacturers boycott, then the products that remain on the market will obtain more market share.

UPL to Support Growth of the Biosimilar Market

There are about 40 US-approved biosimilars, but market uptake has been slow for several reasons. One of the causes of slow uptake is that the manufacturer of the original ('reference') biologic maintains price but increases price concessions/rebates to insurers/PBMs such that on-net, the reference product is less expensive to the payor and its PBM than a biosimilar which has less ability to compete on rebates because of its lower market price.

Biosimilars come to market at a lower price, as they are expected to do, but do not necessarily have the ability to offer the level of rebates provided by the reference product manufacturer which is increasing rebates in order to maintain market share (albeit at a much lower net revenue point). The reference product can do this since it no longer has protection from market competition and would otherwise lose market share and almost all revenue very quickly. Substantially reduced revenue is still revenue when the alternative is no revenue. The result is that the reference product maintains preferred formulary status and maintains market share. This makes financial sense for the health plan/PBM but does not make sense from the patient/consumer perspective since cost sharing is typically determined by the list price of a product.

A board could consider setting the UPL at the price of the average cost of the biosimilars, the lowest-cost biosimilar, or the net cost of the reference product (which may be too low to support new-to-market biosimilars since the reference product net cost undercuts the cost of the biosimilars). The purpose of a UPL in this case is to lower the WAC of the reference product to the point where biosimilars can compete transparently on product cost with the reference product. It will hopefully be difficult for any activity that undercuts open market competition to persist since consumers will know what they should be paying for these products at the point of service and are protected on cost, even if the reference product were to remain the preferred product on formulary.

Budget-Based Upper Payment Limit

A board would work with payors and direct purchasers depending on the drug product to determine the current amount of spending on the disease or diseases treated by the product

that is determined to be an affordability challenge. The total current spend by government programs, private and public payors on the drug product of concern could be considered the "willingness to pay" budget. A board would also need to assess the extent of unmet need and what it would cost to provide access to the product.

The UPL development would roughly follow what Louisiana did in developing its upper payment limit for Hepatitis C treatment for Medicaid and Corrections.

In very brief terms, Louisiana determined the amount it spent on Hep C treatments in the most recent year available for Medicaid and Corrections. That amount was indexed to the project year to produce a budget-based amount for expanding access to treatment in Medicaid and Corrections without uncontrolled spending growth. Multiple Hep C product manufacturers bid on the project and the State worked with the bidders. The product was priced to meet the budget and manufacturers agreed to supply the product at that price to Medicaid and Corrections, without a limitation on quantity.

Another state's situation will be different but there are several key points from the Louisiana experience to bear in mind.

- Know how much is currently spent (beyond just state and local programs and purchasers).
- Know how financial stress of the product manifests for payors and/or for patients.
- Understand the level of product discounts in the market (supplier willingness to discount)
- Lastly, the Louisiana Hep C experience demonstrates manufacturers do not want to cede market share to a competitor even if steep price concessions are required.

Other factors a board should consider in setting a budget based UPL include:

- the drug class and extent of class competition;
- whether the drug will supplant existing drug treatments or not;
- size of current patient population and expected growth in that population; and
- the extent to which a board intends to expand access to the product for patients *and* specifically expand access to the market for the manufacturer.

A budget-based approach will require the cooperation of public and private payors (including employer plans) to get a very good sense of the current 'willingness to spend" on the product as well as a sense of manufacturer's willingness to discount. A budget that is based on willingness to spend provides a variety of options to manage spending on the product. One idea would be to set a UPL below current market, reduce patient cost sharing commensurately and expect a boost in utilization without a lot of savings to payors. Alternatively, a board could decide to use the UPL to reduce both payor and patient spend because the number of product treatment indications has expanded while the product is still priced as a rare disease/very small market drug.

Payor Return on Investment Upper Payment Limit

This approach would be suitable for products that are purported to reduce the total costs of care. When manufacturers price a drug for the value it provides, they may estimate tangible savings such as reduced hospital stays or length of stay, reduced ER spending, reduced testing or office visits, or reduction in disability. They also may estimate intangible savings – such as reduced familial caregiving.

For a payor return on investment approach, the only offsets that should count are medical. Savings that accrue to entities other than the payor – such as society at large-- should not be considered. There are few examples of payments to producers based on the full societal value of the product. It does not happen often because it is not a generally affordable approach to financing access to services. Our healthcare premiums cannot sustain paying for societal benefit product by product, procedure by procedure.

In the return on payor investment approach, to the extent that a manufacturer can actually produce and quantify the factors that went into pricing, a board should review those and consider outside validation of the manufacturer's assessment.

If there are no manufacturer numbers but just the general claim of reducing total cost of care, a board can establish a UPL based on its assessment of the reduction in total cost of care and the return on investment for the payor. A board could decide that payors should start to see offsets or reductions in total treatment costs within a set period of time – say 5 years. If the total cost of care savings is not accruing to payors, then the UPL would be lowered.

This is different from a pay for performance approach where the manufacturer is at risk for the expected outcomes for an individual patient or cohort. Manufacturers return some portion of the treatment cost to a payor. The payor RoI approach is more general and potentially easier to administer.

Other UPL Frameworks

A board may decide to assess existing market provider payment/reimbursement rates, such as Medicare ASP, or publicly available federal program discounts such as VA, federal supply schedule, the Medicaid base rebate formula, and the national average estimated manufacturer discount (which some boards use). A board could review all of these to see if any would improve affordability in the state to the desired degree.

Short List of To-Do's

If available, use All Payor Claims Data (APCD) for creating pool of products that meet statutory

thresholds of the law. APCD is helpful for broad and general analysis. In most states with APCD, it is an incomplete data set and provides very general spending/payment information. It would be a rough proxy for identifying affordability. Knowing the formulary/tier placement across a wide swath of commercial and employer plans, and the cost sharing associated with the tiers, as well as manufacturer patient assistance provides more accurate, robust information, and are clearer proxies for assessing affordability relative to APCD. A board such understand the strength and weakness of the state APCD and determine its best use in board work.[11]

Avoid establishing a UPL that is a direct reference to the cost of a product in another state or country. So-called 'reference pricing' seems to be one of the strongest legs of a Commerce Clause challenge based on the Supreme Court *Ross* decision (2023). Adopting the Medicare MFP is different since it is a national price, a very public price, and a price already present in the state for Medicare enrollees.

Specify in regulations that the state will not enforce UPLs for Medicare B, C, or D provider reimbursements. This should be done without regard to whether the UPL is the same as the MFP for a drug. This is necessary based on case law concerning Medicare preemption.

Enforcement

A Statewide UPL is generally self-enforcing. Suppliers, pharmacies, hospitals have no incentive to buy a UPL product at cost higher than the UPL because subsequent purchasers in the supply chain and consumers will not pay more than the UPL. Health plans have no incentive to reimburse providers more than the UPL. The UPL amount will be widely known in the State; consumers will be aware of the in-state product cost which can be used to assess what they should be charged when paying for a drug.

The potential enforcement challenge could be diversion: a supplier might buy a quantity of UPL product and then sell the product at market price into another state. This will be easy to track once the federal 'track and trace' program is fully implemented and will diminish the feasibility of diversion. In the meantime, a state may want to contract with a wholesaler to specifically manage the physical distribution of UPL drugs in a state.

Of note, wholesalers operate the federal Vaccines for Children program – vaccine purchasing, warehousing, and fulfilling orders from participating providers who vaccinate Medicaid and uninsured children. The current VFC model evolved from depot-style bulk delivery and state distribution of childhood vaccine to participating physicians to the more efficient model we have today. Pediatricians and other private and public sector participating providers order through state VFC offices to restock childhood VFC vaccines at no cost which are then provided free to Medicaid and uninsured, low-income children. The program most likely has operational and administrative policies and procedures that address diversion and can inform the board

[11] Some states may have very high commercial and employer health plan participation in APCD, which could make the data robust. Some state APCD may allow research into formulary placement of drugs across payors. Utility of APCD vary by state.

In addition to preventing diversion and monitoring for diversion, a state office of the Attorney General office would have authority to pursue violations of a state UPL laws and instances of diversion of product to out of state.

Self-Funded Employer Plans

The Supreme Court ruled in December 2020 that states can enact laws that effect ERISA plans so long as those laws do not impact ERISA plan benefits/coverage.[12] The Court said that state healthcare rate setting is a permissible state action, even if it costs ERISA plans more as a result. An upper payment limit *is* healthcare rate setting and applies to all financial transactions of a drug intended for use in a state: purchases, payments, billings, and reimbursements by state licensed providers and suppliers and most health plans. ERISA plans are in the rate setting mix like other health plans. A statewide upper payment limit would require state licensed suppliers and providers to abide by the UPL when buying, selling, billing, and reimbursing for a UPL drug product. Pharmacies must dispense and bill at the UPL to all customers and payors. It is very important that commercial and employer plans work with the board to ensure that the UPL is sound – at or below the current insurer net cost for the product. Additionally, consumers will want to see the benefit of a UPL, even when UPL products are subject to copays (in contrast to coinsurance). Health plans should work with a board on this aspect of UPL as well.

Medicare

Parts B (physician administered Rx), Part C (physician administered and retail drugs) and Part D (retail drug)

State law cannot affect Medicare plans in ways that run counter to the purposes of the Medicare program, or as in ERISA law, affect benefit coverage. To that point, drug cost containment has been the hallmark Medicare policy for many years. State efforts to lower prescription drug costs mesh with the goals of the Medicare program.

States cannot regulate Medicare C and D plans in areas that the federal program already regulates, which is a broad preemption of state law. Medicare policy until 2026 will remain centered on what Medicare B and Medicare plans *pay* for drugs, not what providers *bill* for drugs. Regarding Medicare, a UPL specifies what providers bill for drugs.

States cannot require that Medicare B, nor C and D plans reimburse pharmacies and providers at the UPL. However, state rate setting rules can require state licensed providers to bill at no more than the UPL – to consumers at the point of service and their insurer. If the presumption is that the UPL will be less than market price, Medicare will benefit from reimbursing providers based on the UPL billing.

[12] The Rutledge decision has more nuance than provided here such as state law/rule cannot target ERISA plans specifically (to the exclusion of other health plans) and cannot unduly burden multistate plan administration. But that regulating ERISA vendors, such as PBMs which also work for a variety of different classes of health insurers and government programs, is not in and of itself a violation of ERISA.

Upper Payment Limits

When the new Medicare Maximum Fair Price (MFP) is implemented in the market in 2026, Medicare B, C and D will pay providers and pharmacies no more than the MFP. At that point, a board probably will not be able to establish a UPL for a drug where the UPL is different than the MFP because it would complicate the operations of pharmacies, physicians, clinics, and hospitals which serve both Medicare and everyone else.

If a state were to establish a UPL on an MFP drug where the UPL is different than the MFP,

- Medicare plans and beneficiaries could have to be excluded from the UPL (but benefit from the MFP),
- Different supply chains may be required for the same drug,
- State residents would have access to different payment limits for the same drug at the same pharmacy,
- Dueling payment limits could create significant billing and other administrative burdens on dispensing and administering healthcare professionals.

This issue will come more into focus as the Medicare MFP program develops, particularly if boards would intend to establish UPLs that are different in cost than the MFP for a drug.

The logical thing for a board to do would be to make the Medicare MFP the statewide UPL, applicable to all the non-Medicare state residents. This would leverage the work of Medicare to provide cost relief to all residents of a state unless there is guidance from the federal government about the nexus between UPLs and MFPs.[13]

[13] Based on current Medicare price negotiation guidance (2023), a pharmacist or physician will buy an MFP drug through routine supply channels at market prices, Medicare will reimburse at the lower negotiated price, and the pharmacist or other provider will have to provide documentation to a federal program vendor that will issue a reimbursement for the difference between market price and the Medicare negotiated amount. Making the MFP the statewide UPL should be able to reduce the administrative burden on pharmacies and providers since they will acquire at the UPL and bill at the UPL. Separate reimbursement/rebate processing will not be necessary.

Selecting Cost Review Eligible (CRE) Drugs and Drugs for Cost Review (CR drugs)

Most state PDAB laws anticipate a process of creating a universe of drugs eligible for cost review (cost review eligible or **CRE**) and from the **CRE** group, a subset of drug that will undergo cost review (**CR**). Some state laws require a board to identify all drugs that meet the cost thresholds of the state law while other state laws specify the cost thresholds and allow a board to explore affordability challenge products within those parameters without having to identify every drug that meets the threshold(s). The first subsection below provides suggestions on how to establish the universe of **CRE** drugs and the subsequent section contains suggestions for culling **CRE** drugs down to a list of drugs for which a board wants to undertake a cost review (**CR**). The following is illustrative only. Additionally, a board will have to decide the purpose of each component or metric.

Managing Workload and Workflow

- Board may want to establish the frequency/periodicity of the full process of looking at drugs that meet statutory and other board-determined thresholds as the basis of a list of **CRE** products. Board should also decide if **CRE** list creation will support one or more rounds of determining products that should undergo a cost review (**CR** drug**).** The decision may rest on how often the **CRE** process is likely to produce a substantially different set of drug products.
- A board could establish numerical targets or limits for:
    - A maximum number of drug products that are **CRE** from among all drugs that meet statutory thresholds
        - this can help manage the workload if a board believes there will be hundreds of drugs that meet the trigger thresholds specified in statute.
    - A maximum number of products that will undergo a cost review (**CR** drugs) in a cycle.
        - This can help manage the workload
    - A maximum number of products to which a UPL could be applied in a cycle.
        - This can help manage workload
- A board should retain its ability to alter or eliminate the numerical targets once a board has experience conducting the entire process.
- Depending on state law which requires a board to identify all (or some) products that meet the statutory cost triggers and other board-established thresholds for brands, biosimilars, generics. A board could specify:
    - Data sources for its work such as publicly available price increase and new drug launch price databases of other states, changes in the Medicare Average Sales Price data, subscription price files. *Claims data from the state all payor claims database (APCD) may not be the most accurate basis for determining whether a*

drug product meets the statutory thresholds. There are a number of confounding factors in using APCD to track price increases.

    - If statute requires a board to know the launch price of a product for purposes of a **CRE** or **CR** drug, and the drug has been on the market for such a long time that finding the launch price is difficult and resource intensive, a rule to address this limitation may be helpful, such as 'launch WAC' is the earliest date for which a reasonably accurate WAC can be established.
- If the state law requires a board to identify 'other products that are thought to be creating financial challenges' to consumers and/or the state healthcare system, a board may want to specify information sources and processes for identifying these drug products.
    - Potential Sources –
        - consumer complaints to a board through some mechanism that can be widely known and widely used by consumers,
        - health plan concerns,
        - publicly available information on adverse patient outcomes resulting from inability to pay.
    - Determine how these 'other products' will be (and will not be) incorporated in the **CRE** process.
    - A board may want to specify that there may not always be such a drug for consideration.

Process to Identify Cost Review Eligible (CRE) Drugs

- Winnow the list of **CRE** products to meet requirements of numerical limit (per above).
    - If a board sets a maximum number of **CRE** products per above, then consider
        - Raising the monetary threshold for brand/biologic Rx above the $30,000 or $60,000 statutory threshold.
        - Consider total or net health plan(s) spend on the products that meet statutory thresholds and include **CRE** drugs are the highest net spend drugs on the list until the numerical cut-off is reached.
    - Identify products with high consumer costs.
        - Health plan formulary tiering and utilization management indicate a cost problem. Use health plan tier placement to represent consumer costs *rather than* claims data to estimate average consumer out of pocket spend across health plans. Obtain Rx-specific formulary information from sources other than APCD, which together, are likely to be more representative of patient cost sharing per course of treatment. A board could consider private and or public information.
            - voluntarily provided (or required) submission by PBMs for State carriers/health plans and ERISA plans.

    - There is no need to publicly identify the plans associated with specific cost share levels in the analysis.
- public sources of formulary design/tiering/utilization management such as:
    - CMS Medicare Part D plan finder for in-state plans;
    - State exchange/marketplace plan query;
    - Medicare B Average Sales Price (20% is the cost share amount in Part B); and
    - State employee plan formulary placement and utilization management.
- Define what it means if the drug is not covered by one or more health plans. Is that a signal of an affordability problem? Should noncoverage mean an 'automatic include' or 'automatic exclude' from **CRE** or **CR** process?

Process to Identify Cost Review (CR) Drugs

Factors used in determining whether a product is cost review eligible may be applicable later in the actual review of a selected product.

- Select **CRE** products that are used by the greatest number of people.
- Select **CRE** products with the greatest number of treatment uses ("indications")
- Select **CRE** products that are not covered by some board-determined number of health plans.
- Select any **CRE** products that have the high formulary tier placement among the preponderance of health plans.
- Select **CRE** products with significant individual patient cost sharing support (in the tens of thousands of dollars per patient).
- Select **CRE** products with significant estimated health plan rebate levels as a percentage of WAC.
- Select **CRE** products that have been withdrawn from the market and replaced by an authorized generic priced at the same WAC as the withdrawn product.
    - This may indicate a strategy to evade large Medicaid rebates in excess of 100% of the price.
- Select for **CRE** products that have come to market with two different list prices for the same dosage, form, and strength.
    - This may indicate a type of insurer/PBM market dysfunction that raises consumer costs.
- Consider whether or not to exclude from **CR**, a **CRE** product that meets the Medicare negotiation exclusion criteria for small biotechs for the first three years of a board's operation, as provided in the Medicare law relative to the Medicare early years of operation.

- Exclude from **CR** a **CRE** product that already has a Medicare Maximum Fair Price (MFP) or any product that is in the mix for Medicare negotiation. (When developing rules and processes for an Upper Payment Limit, a board can stipulate that a Medicare MFP product is automatically assigned a UPL that is the same as the MFP. This extends the efforts of Medicare to all state residents.)

Determining if a Drug is/will be an Affordability Challenge

The following scenarios may indicate that a drug is or will create an affordability challenge for state residents and/or the healthcare system. This is not an exhaustive list of scenarios but rather a starting point for board consideration.

- Assess **CR** products for health equity considerations when applicable and feasible.
  - Possible data sources, surveys of treating providers, pharmacies, patient groups, medical lit, original epidemiological analysis. CO and OR have already identified and used county level data that is a proxy for equity.
  - Demographics of populations indicated for the drug such as age, race, ethnicity, income, sources of coverage. (Example would be Hep C, which is thought to be most prevalent among people on Medicaid, in Corrections, and who are uninsured).
- Assess general impact on patients/consumers of **CR** product.
  - Estimated number of residents indicated for the drug or are currently using the drug.
  - Estimated prevalence of the condition compared to number of people receiving treatment with the product.
  - Rx abandonment rates for the product.
  - Treatment adherence rates of the product.
- Systematically evaluate how commercial and employer health plans treat the **CR** product
  - high cost- sharing tiers.
  - utilization management.
  - covered by all or most plans?
- Assess if the **CR** product
  - Is highly rebated and/or
  - Comes with large manufacturer patient cost sharing assistance and
  - Is on a high cost share formulary tier among a board-determined percentage of plans.
- Assess if a **CR** product is near patent expiry or already off-patent (board to define "near") and which has or is expected to have therapeutic competition.
  - These near-expiry drugs are often highly rebated to maintain market share even after the first generic or biosimilar comes to market which impedes uptake of the lower cost generic or biosimilar.

- The net cost of the off-patent product is less than the cost of the generic or biosimilar.
- The patient cost is higher for the preferred, off-patent product than for lower priced competitors.
- A board may want to look into this market dynamic more carefully through CR

Summary

There are different ways to approach assessment of affordability and setting an upper payment limit for a prescription drug. It is important that a board's processes are clear so that stakeholders can understand, with some level of detail, how the board will proceed, what metrics it will use to assess affordability and how it could establish a UPL. A board should also be clear that the process needs to be flexible because the data sources, metrics and considerations may vary based on the drug or drugs of concern.

Another important consideration is reliability of data used, including how data is curated and applied.

As suggested earlier in this paper, the board should be proactive and *solicit* the input of stakeholders – in addition to diverse patient views. There are stakeholders with specific knowledge of the product, the patients, and the affordability of a product. For instance, commercial and employer health plans have experience with product utilization and costs. These plans have made business decisions based on costs and utilization. Besides the business experience, plans also have clinical understanding of the product. The knowledge of community pharmacists would be beneficial to a board. They have direct experiences and knowledge about patient access and the economics of a drug product from the pharmacist's view including manufacturer assistance programs.

The work of a board is difficult, to say the least. It is important for a board to be clear how it will operate – how it will develop the list of cost review eligible drugs, then how it will cull that list to drugs that will undergo cost review, metrics for affordability for patients and the healthcare system, and any other metrics such as market operation or market dysfunction.

All of this is important for residents and stakeholders, which includes the pharmaceutical industry. As of April 2024, Colorado has been sued by Amgen over board process (among other complaints).

ERISA and Dormant Commerce Clause

How US Supreme Court Decisions on ERISA and Dormant Commerce Clause Create a Path Forward for Substantive State Healthcare Financing Reforms, Notably Prescription Drug Upper Payment Limits

Horvath Health Policy, Innovations in Healthcare Financing. July 2023

The one of the purposes/goals of the ERISA[68] law is to protect multi-state employers from the vagaries of different state laws that would affect self-insured employer retirement funds and employer sponsored health benefit coverage. Traditionally, these self-funded plans were large multi-state corporations but in recent years, smaller and smaller companies are self-insuring for employee health benefits. The result of this trend is that ever larger proportions of a state's residents have health coverage where consumer protection rests with the federal government and states have not been able to affect that market in meaningful ways in addressing statewide healthcare cost concerns.

Additionally, a body of case law has built up over me concerning the limits of states' ability to regulate commerce beyond their state borders. The Constitution places regulatory authority for interstate commerce with the federal government. The litigation and court rulings – which go back more than a hundred years – determine the extent to which states can enact laws or policies that implicate commerce outside the state and when those laws or policies run afoul of the Constitution. This is referred to as the Dormant Commerce Clause (DCC). Ex-state commerce at issue in these DCC cases can concern policies which disadvantage out-of-state rivals relative to in-state businesses or policies that place undue burdens on businesses that operate in more than one state. In the later situation, the DCC is similar to one of the purposes of the ERISA law.

Together, ERISA preemption of state laws and Dormant Commerce Clause court rulings have quite hobbled state innovation in healthcare coverage and financing policy over the years.

Recently, however, the US Supreme Court has taken on important and diverse ERISA and DCC cases concerning state laws which may impact large national (indeed global) industries. What is striking about these recent ERISA and DCC decisions is that they have the effect of narrowing the field of what constitutes an ERISA or a DCC violation. The decisions have been supportive of state ability to address residents' needs even when the impact of the laws extend beyond state boundaries or cause increased costs for an employer plan or a multi-state business. The relevant cases are Rutledge (Arkansas AG) v Pharmacy Care Management Association and National Pork Producers Council v Ross (the CA Secretary of Food and Agriculture).

[68] Employee Retirement Income Security Act, 1974

ERISA/Rutledge

In brief, the Rutledge decision on ERISA preemption provides that a state-regulated entity which is also a vendor to an ERISA plan cannot avoid state regulation of its operations solely because it is a vendor to an ERISA plan. The ruling specifically cites states ability to set healthcare payment rates.

The ruling affirms the state actions that continue to be preempted by ERISA. States cannot regulate what services must be provided (coverage mandates) but can extend laws that impact the state market more generally – such as insurer/PBM business practices even though those regulations may cause the costs of an ERISA plan to increase along with the costs of other insurers in the state.[2]

There is a slightly older decision," Gobeille v Liberty Mutual" (2016) where SCOTUS found in favor of the ERISA plan objection to reporting data to the Vermont All Payer Claims Database. The Court found that the administrative burden of complying with various state claims payment, enrollee data, and other plan data reporting laws affected the heart of plan administration.

A PDAB model bill upper payment limit is a requirement on state licensed providers (including wholesalers) to buy and bill at the UPL. The ERISA plan benefits and basic administrative functions are not affected.

Dormant Commerce Clause/Ross

The Ross decision adds also clarifies what state regulatory authority is protected. The decision goes to lengths to describe the situations which would violate the DCC (none of which were applicable to the particular situation of the pork producers in this case).

At issue was a successful public ballot initiative to ban the sale, in California, of pork products produced by inhumane treatment of pigs. Inhumane treatment is defined in the law and mirrors standards of several other states. The National Pork Producers Council sued California in Federal Court contending the law violated the Constitution's Commerce Clause – a condition referred to as the (Dormant Commerce Clause).

The Court found that California law does not advantage in-state producers to the detriment of out of state competitors for state business because there are in-state pork producers who must comply.

- A statewide UPL would not favor in-state companies relative to out of state competitors wanting to compete in the UPL state since in-state entities are bound by the same law.

The Court found that California law does not, per se, impermissibly control commerce outside of California because pork producers can choose not to sell in the State. In terms of exceptional costs/burdens of compliance, in-state producers face the same compliance costs and plaintiffs did not quantify those costs.

- A UPL does not create new operational complexities for pharmaceutical manufacturers nor for the full supply chain. All the operational components needed to implement a UPL are already entrenched in the industry business model. A UPL has no in-state/out-of-state an-competitive or discriminatory effect on the pharmaceutical industry.

The Court notes that in our national economy many, if not most, state laws have the practical effect of impacting business and business behavior outside the state. The Ross decision cites examples of tax law, environmental law, securities laws, tort laws.

The Court did not support Pork Producers claim that the burdens on industry and interstate commerce clearly exceeded the benefit of the law to State consumers. Pork producers did not provide any compelling evidence of the excessive costs and that the Court was not in a position to decide for itself what the consumer benefit was from more humanely treated pigs; the Court noted that the State law stemmed from a public vote on a statewide ballot proposition that was overwhelmingly supported by voters.

The Ross ruling does seem to reaffirm that costs to out-of-state industries is not in itself a defining feature of a DCC violation. The majority opinion seems to affirm that the core of a DCC violation is creating an-competitive trade between states – including what we call 'reference pricing' – requiring a business to provide the same price in-state as the business has provided outside the state. Then there is the Frosh decision, which is cited in Ross and supported in Ross (and the SCOTUS refused to hear Maryland's appeal of the lower Court's decision). In Frosh, the Maryland DCC violation occurred because the law seemed to require (a very limited number of) generic manufacturers to potentially change their list prices across the country (directly affecting out of state commerce).

Please note, in this Ross decision, SCOTUS *reaffirmed* the application of the DCC to situations where a "price control or price affirmation" law which ties the price of a product in one state to the price of the product out of state.[69] Even though the Frosh case was only decided in the 4th Circuit, the use of the case in the Ross decision together with the SCOTUS refusal to hear the case, should cause state policymakers thinking about Rx reference pricing to craft their policies very carefully.

Summary

These two decisions should help state policymakers to feel more confident in statewide healthcare rate setting – upper payment limits.

An outstanding legal issue that the industry will likely pursue in response to an upper payment limit is violations of federal patent law – the Constitution's Supremacy Clause. There is a ruling (PhRMA/BIO v

[69] There is the PhRMA/BIO v District of Columbia case decision from 2004, PhRMA v Walsh in 2003 and the AAM v Frosh decision of 2018 that deal specifically with DCC and Rx, which is distinct from other DCC cases concerning beer, milk or other commodities that created dormant commerce clause case law in the prior century.

Washington DC) where the Court found that Congress intended inventors to have unlimited ability to profit from innovation and the DC law that specified the manufacturer price of the drug in the City had to be no more than the price in several European countries. The case – argued by patent folks in federal patent court -- looked only at patent law. If there is a challenge to UPLs based on patent law, a state in that case should use federal healthcare/Rx laws to show that Congress does not intend that patent rights supersede the need for affordable prescription drugs. Examples of Congress' intent that patent rights should not impede access to healthcare include thirty years of the 340B program and the new Medicare negotiation program. Both these programs would seem to indicate that when it comes to access to healthcare and affordable healthcare, Congress certainly has expressed there should be limits on the profits from patent protected pharmaceuticals.

2024

State Prescription Drug Affordability Board and the Dormant Commerce Clause (DCC)

AMGEN CHALLENGE TO COLORADO PRESCRIPTION DRUG AFFORDABILITY BOARD

JANE HORVATH

HORVATH HEALTH POLICY |

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State Prescription Drug Affordability Board and the Dormant Commerce Clause (DCC)

Amgen Sues Colorado on DCC Grounds:

In general, a prescription drug affordability Board (PDAB) would have authority to establish an all-payer, all-purchaser, statewide upper payment limit (UPL) for sales, purchases, billing and reimbursement of certain high-cost brand or generic drugs intended for sale in the PDAB state.

The Supreme Court Ross decision in 2023 diminished the frequency of industry claims that a UPL violates the Commerce Clause. However, Amgen raised the DCC in its March 2024 lawsuit against the Colorado PDAB for its cost review of Enbrel, so it is worth looking at UPLs and DCC again

What is the Constitution's Commerce Clause and What is the Dormant Commerce Clause?

The Federal government, by virtue of the Constitution's Commerce Clause, regulates commerce between the states. States regulate in-state commerce. State regulation can have ancillary out of state business impacts that do not reach a threshold of regulating interstate commerce. State authority to regulate commerce is not written in the Constitution but state authority to regulate commerce, or the limit of that authority, has evolved over time through court decisions and is referred to as the Dormant Commerce Clause (DCC).[70]

Because the branded pharmaceutical market segment is so complex and has been so opaque, the pharmaceutical industry has been able to capitalize on lack of knowledge about business practice in its lawsuits alleging violations of the Commerce Clause by states when enacting drug cost containment laws. The industry has used the complexity of its business model to make the point in court that virtually any state law is onerous for them, upends their standard commercial operations, resulting in excessive burdens on business.

UPLs do not place an undue burden on pharma industry operations nor impermissibly impact interstate commerce:

States are not allowed to unduly burden interstate commerce or negatively affect business competition outside the state for the benefit of the in-state competitors. The Courts have recognized that in today's national and global economy, almost any state regulation has impact outside a state, but that does not mean, per se, the regulation exceeds state authority. Amgen simply says that healthcare rate setting -- limits on what licensed providers and suppliers can bill and pay for a costly drug-- wholly regulates financial transactions out of the state. Amgen

[70] Industry also claims drug cost containment violates their patent rights to unfettered price and profit, which triggers the Constitution's Supremacy Clause where federal law supersedes state law and makes other claims as well which are beyond the scope of this paper.

further states that there is no situation in which healthcare upper payment limit rate setting is acceptable.[71]

The Supreme Court has, over the years, developed a far more nuanced interpretation of the DCC.

The PDAB and UPL authority are based on the long-standing state practice that regulates what consumers will pay for vital public utilities and services. Additionally, the UPL leverages the business model US pharmaceutical companies already use to ably and deftly accommodate the demands for price concessions among scores of different providers/purchasers and health plans throughout the country and for numerous drugs in a manufacturer's product line. Both these factors contribute to PDAB and UPL compliance with dormant commerce clause caselaw and are described in more detail below.

Public Service Commission Model:

Public service commissions in all 50 states set consumer payment rates for vital services such as electric, natural gas, taxi, and/or telecommunications services. These commissions regulate charges for products and services that (most often) come from companies and facilities located out of state. These same corporations sell their services and products in multiple states. As a result, what any one company can charge and what consumers will pay any one company is different in each state. This does not violate the DCC.

Like the function of a public utilities commission, a PDAB would set healthcare payment rates (upper payment limits) for consumers and state licensed healthcare entities (wholesalers, local distributors, hospitals, physicians, pharmacists, and insurers).[72]

- Like a public service commission, a PDAB protects state residents from exceptional costs that threaten quality of life or health.
- Like a public service commission, a PDAB does not favor in-state businesses to the detriment of out of state businesses.
- Like a public service commission, any small impact on a manufacturer's out of state operations (negotiations with wholesalers) is incidental to the significant benefits to health and welfare of state residents.
- Like a public service commission, a PDAB sets payment rates only on services provided to individuals present in the state.

[71] Amgen consistently and persistently refers to state upper payment limits as PRICE CONTROLS, which are not acceptable per caselaw. Because UPLs are in fact, state healthcare rate setting, the phrase 'price controls' is replaced with 'healthcare rate setting' in this paper for similar, if oppositional, effect.

[72] Each bullet point represents an aspect of a DCC court decision setting standards for evaluating Commerce Clause violations.

- Like a public service commission, a PDAB upper payment limit does not impact the price of the service or product in another state, nor the national 'list price' of a drug manufacturer.
- Like regulated regional or national electric, gas, or telecommunications services, drug companies rely on wholesalers or specialty distribution systems to manage the product supply going to a specific state or specific purchasers.
- Like a public service commission, the PDAB mission is to maintain (or increase) consumer access to vital services and products through affordability.

The Industry Business Model:

Biopharmaceutical companies use price concessions to improve product market position and sales.

Price concessions are provided to direct purchasers as well as to health plans and health plan vendors (pharmacy benefit managers). Price concessions are provided through different mechanisms for health plans/PBMs and direct purchasers. The industry business model is flexible and adaptive; meeting market demand in a state for UPL drug would require no changes in operations (only a change in attitude in favor of affordability and access).

A UPL product will most likely to be brought into a state by a wholesaler or wholesalers. The wholesaler(s) will have negotiated with the manufacturer to buy the drug at less than the UPL (a discount off the wholesale [aka list] price) which is a standard wholesaler/manufacturer transaction. The wholesaler(s) will supply the UPL product in the state to direct purchasers (such as pharmacies, clinics, physician offices). A state may decide to contract with a dedicated wholesaler to supply UPL products.

Another approach would be for wholesalers to purchase the product without regard to the UPL, and when distributing the UPL product, sell in-state at the UPL. In this instance, the wholesaler would have an agreement in place for the manufacturer to reimburse the wholesaler for the difference between what the wholesaler paid the manufacturer and the UPL amount the wholesaler was able to bill. It is a routine type of transaction that allows the manufacturer to make price concession deals with purchasers (such as big hospital systems), without getting into the drug supply/delivery business. Alternately, a hospital system may buy at market from a wholesaler and invoice the manufacturer for a rebate (per a contract). There are different ways that price concessions can be delivered/obtained but they are all standard procedure. There are other ways to convey price concessions as well.

- Entities that participate in the federal 340B drug discount program will continue to use their routine supply channels for the drug, since the 340B acquisition cost will be less than the UPL. Standard procedures.

- If a manufacturer uses a specialty pharmacy for product distribution, purchasers in the state will use that designated specialty pharmacy for ordering supply.

- If large health plans/PBMs or large hospital systems have price concession agreements with the manufacturer of a UPL product that reduce the drug cost further, those agreements are operationalized through rebates after the UPL drug is dispensed or through discounts applied at the time of the sale. Standard procedure.

A UPL does not present any exceptional difficulty for a manufacturer or the supply chain. The 'out of state' financial transaction between the wholesaler and the manufacturer is routine. The manufacturer may have contracts for more significant price concessions than one state's healthcare upper payment rate.

Past and present industry challenges to state Rx cost containment laws

Two older Court rulings concerning industry, the District of Columbia and Maryland[73] found that regulating the manufacturer's prescription drug price is a violation of the Commerce Clause. Most recently, a court barred Minnesota from enforcing a law that protects consumers from certain generic drug price increases pending the outcome of the lawsuit. Illinois has also been sued for a similar law, although its law is more tailored to generic products whose manufacturers operate more like branded industry.

The price gouging laws in Maryland, Minnesota, and Illinois cited in the Amgen filing provide for retrospective enforcement against generic and off patent brand manufacturers for price increases. These laws require operational mechanics completely different from those required to implement an upper payment limit. The generic industry trade association, Association of Accessible Medicines sued over the Minnesota price gouging law but did not sue over the UPL law that was enacted in the same omnibus legislation.

Relevant non-pharma DCC case

[73] Association for Accessible Medicines v. Frosh, 887 F.3d 664 (4th Cir. 2018) (state price gouging law barred by dormant Commerce Clause); Biotechnology Indus. Org. v. District of Columbia, 496 F.3d 1362 (Fed. Cir. 2007) (District imposed price limits on manufacturer was ruled a violation of dormant commerce clause).

Perhaps most important is a more recent DCC ruling by the US Supreme Court that did not concern prescription drugs.[74] In this decision, the Court examined all the possible ways that a state law would violate the Commerce Clause and found that the concerns of the plaintiffs did not meet any of the DCC violation thresholds. The challenged California law banned the sale of pork products in the State if the animals were not treated humanely. The California law is highly similar in effect to a state UPL. It is prospective, it requires state-licensed entities to be responsible to operationalize/enforce, it does not compel out of state suppliers to participate in the market, and the health, the law applies equally to instate and out of State producers, and welfare benefits to state residents was found to exceed any burden on out of state pork producers.

Like the California pork product law, a statewide UPL also:

- Provides benefits to consumer health and safety that outweigh the impact on trade outside the state;
- Does not benefit in-state business to the detriment of out of state competitors operating in the state;
- Does not affect the manufacturer national list or the price to any purchaser of drugs destined for another state;
- Does not exclusively target the in-state sales of businesses located outside the state;
- Has only incidental impact on manufacturer operations outside the state.

Summary:

The Amgen lawsuit alleges multiple violations of the Constitution. This document addresses the Commerce Clause in detail since it is likely to come up again in another state. Other documents will address the several other issues raised by Amgen in their lawsuit.

[74] Pork Producers v Ross, May 2023