Oregon Prescription Drug Affordability Board

350 Winter Street NE, Salem, OR 97309-0405 | 971-374-3724 | pdab@dcbs.oregon.gov | dfr.oregon.gov/pdab

Agenda

Date: **November 16, 2022** | *Time*: **9:30 a.m.**

Meeting name	**Prescription Drug Affordability Board**
Meeting location	Virtual
Zoom link	Click here to register for the meeting

Board Members: Chair Akil Patterson; Vice Chair Shelley Bailey; Dr. Daniel Hartung; Dr. Richard Bruno; Amy Burns, Robert Judge (A); Dr. Rebecca Spain (A), John Murray (A)

*(A) denotes Alternate Member

Staff: Ralph Magrish, executive director; Cortnee Whitlock, policy analyst; Stephen Kooyman, project manager; Yasu Tanaka, data analyst, Melissa Stiles, administrative specialist; Joanna Tucker Davis, counsel; Pramela Reddi, counsel

	Subject	Presenter	Time Allotted
☐	Call to order, roll call and approval of minutes	Chair Patterson	5 minutes
☐	Executive Director's program update	Ralph Magrish	5 minutes
☐	Patent Law Presentation by Initiative for Medicines, Access & Knowledge (I-MAK)	Tahir Amin, Co-Executive Director	20 minutes
☐	Board Questions and Answers	Tahir Amin	10 minutes
☐	Board Discussion of Final Draft Reports for: Rx Generic Drugs Report (20 minutes) Rx Distribution and Payment System Report & Recommendations (20 minutes) Price Trends for List of Rx & Recommendations (15 minutes)	Cortnee Whitlock	55 minutes
☐	Board Approval: Final Model Rules for Rulemaking and Public Records Requests	Cortnee Whitlock	10 minutes
☐	Announcements	Ralph Magrish	5 minutes
☐	Public comment	Chair Patterson	10 minutes
☐	Adjournment	Chair Patterson	2 minutes

Next Meeting

December 14, 2022, at 9:30 a.m.

Accessibility

The meeting is accessible to persons with disabilities. A request for hearing impaired assistance and accommodations for persons with disabilities may be made to Melissa Stiles by email at pdab@dcbs.oregon.gov or by phone at 971-374-3724, with at least 48 hours' notice.

Public Comment

Oral Testimony

To sign up for public comment, email your request to the Prescription Drug Affordability Board at pdab@dcbs.oregon.gov 24 hours before the meeting. Include your name, organization, and the related agenda item.

Written Testimony

Email your written testimony to the Prescription Drug Affordability Board at pdab@dcbs.oregon.gov 72 hours prior to scheduled meeting. Any written comments after 72 hours will be included for board consideration at the next meeting. Include your name, organization, and the related agenda item.

Open and Closed Sessions

All board meetings except executive sessions are open to the public. Pursuant to ORS 192.660, executive sessions are closed, with the exception of news media and staff. No final actions will be taken in the executive session. When action is necessary, the board will return to an open session.

Oregon Prescription Drug Affordability Board

Oregon Prescription Drug Affordability Board Meeting
Wednesday, October 19, 2022
Draft Minutes

Call to Order and Roll Call
Chair Akil Patterson called the meeting to order at 9:32 a.m. and asked for the roll call.

Board Members Present: Vice Chair Shelley Bailey, Dr. Richard Bruno, Dr. Amy Burns, Dr. Daniel Hartung, Chair Akil Patterson, Robert Judge (alternate), Dr. Rebecca Spain (alternate).
Board Members Absent: John Murray (alternate) due to hosting a vaccine clinic at his pharmacy.

Approval of the Minutes
Chair Akil Patterson asked if board members had any changes to the September 21, 2022, minutes on Pages 3-7 in the agenda packet posted online: https://dfr.oregon.gov/pdab/Documents/20221019-PDAB-document-package.pdf. Vice Chair Shelley Bailey moved to approve, and Dr. Daniel Hartung provided a second. The chair asked for a voice vote.

MOTION by Shelley Bailey to approve the September 21, 2022, minutes.
Board Voice Vote:
Yea: Richard Bruno, Amy Burns, Daniel Hartung, Shelley Bailey, Akil Patterson.
Nay: None.
Motion passed.

Program Update: Executive Director Ralph Magrish welcomed new board members Amy Burns and John Murray, confirmed by the Senate in September. Dr. Burns, Grants Pass, is director of pharmacy services at a coordinated care organization serving Oregon Health Plan members in Southern Oregon. John Murray is the owner of an independent pharmacy in Boardman. The board looks forward to the contribution of their work and all the experiences and insights they bring.

Ralph Magrish let the board know the conflict of interest form has been posted to the web as a fillable PDF, which will be easier to fill out and return to staff. Additionally, the online comment submission form has been updated with instructions. Staff is contracting with ICER, the Institute for Clinical and Economic Research, in preparation for the affordability reviews, along with acquiring health data from SSR Health. At the November meeting, the board will hear from Tahir Amin, co-founder and CEO of IMAK, presenting on international prescription drug patent law and implications on drug costs.

The Drug Price Transparency (DPT) program will hold its annual public hearing on Dec. 1, from 10 am to 12 pm. DPT is directed by statute to receive manufacturer pricing reports related to new drugs that cost more than $670 on launch. In-state insurance carriers also report to the Division of Financial Regulation the top 25 most costly and prescribed drugs and the impact of those drug costs on premium rates. New data points collected for this year include the total dollar amount paid for drugs by the insured and by the insurer after rebates and other price concessions. The December 1 hearing will also include consumer reports and personal stories from Oregonians. Consumers who would like to report price increases and tell their stories can visit the transparency website: https://dfr.oregon.gov/drugtransparency/Pages/public-hearings.aspx. The annual hearing will include panel discussions on insulin pricing presented by National Academy of State Health Policy (NASHP), Cambia/Regence, the Oregon Public Interest Research Group (OSPIRG), and Civica Rx. A second panel will be on

PBM rebate transparency presented by Pharmaceutical Care Management Association, Pharma, Healthcare Distribution Alliance, and an independent pharmacist from rural Oregon. The DPT program is preparing a legislative report with recommendations for legislative changes to contain the cost of prescription drugs.

Upper Payment Limit: Lila Cummings, director of the Colorado Prescription Drug Affordability Board, gave a presentation on upper payment limits, located on Pages 14-38: https://dfr.oregon.gov/pdab/Documents/20221019-PDAB-document-package.pdf. She discussed the board's rulemaking process, establishing affordability review criteria, upper payment limit methodology, research methods, stakeholder input, reporting requirements for using savings, and carrier use of savings formula. Andrew York, executive director of the Maryland Prescription Drug Affordability Board, also presented slides located on Pages 39-55: https://dfr.oregon.gov/pdab/Documents/20221019-PDAB-document-package.pdf. He discussed the board generics report, pharmaceutical distribution and payment system report with recommendations, a cost review process, and the board's plan to develop and submit an upper payment limit action plan, transparency program, and insulin affordability program.

Chair Akil Patterson asked if upper payment limits actually help and what is the evidence they would help protect residents of Oregon, Maryland, and Colorado. **Andrew York** said he was responding personally, not on behalf of the board. He said upper payment limits would have an impact because they set the amount that would be paid for a drug. It is a novel policy and these boards are the organizations that can do this work. An example of upper payment limits are the Medicaid prescription drug negotiations, which are part of the Inflation Reduction Act. **Lila Cummings** said the way Colorado's upper payment limit is being drafted, it would apply directly to the consumer and to the carrier reimbursement. How upper payment limits impact manufacturers through negotiations is an area outside the board's purview. **Andrew York** said part of the challenge for these boards is to make sure what they implement has the desired effect. Part of the exercise is defining terms.

Chair Patterson said the Oregon Prescription Drug Affordability Board does not currently have upper payment limit authority, but the board wants to gain understanding if the legislature gives the board that authority in the future. The chair asked if the Maryland board initially had the authority to set upper payment limits. **Andrew York** said the Maryland Prescription Drug Affordability Board has the authority to set upper payment limits for state and county governments, including state employees and procurements.

Robert Judge asked if they considered the best price in their upper payment limit discussions. **Andrew York** said yes, the board absolutely needs to consider the best price as they go through the process of setting upper payment limits. Generally, the best price is a substantial discount. **Lila Cummings** agreed and said when the Colorado board is considering upper payment limits, staff will include information from the all payer claims database, publicly available fee schedules, and what some private payers may have paid. **Robert Judge** said since much of the information is voluntarily supplied, how does the board account for a supply chain that lives comfortably in the dark when determining drug costs. **Lila Cummings** said Colorado uses publicly-available list prices - what was actually paid - or wholesale acquisition costs, knowing they will be unable to get at each point of the supply chain. **Andrew York** said there are strong confidentiality protections in the board's work and with that comes the opportunity to get some data points that are not publicly accessible. One of the Maryland board recommendations is implementing a transparency program. The board does not know the net price of a drug or even the magnitude. As part of this transparency program, Maryland will learn from the work happening in Oregon and other states. Part of the reason these issues exist is because of this opacity and complexity. Trying to shine some sunlight there is one of the things these boards can do.

Chair Patterson asked about upper payment limit impact on 340B clinics. **Andrew York** said 340B programs provide drugs at a discounted cost to entities that serve high-needs populations. It allows them to get drugs for

significantly discounted prices. They often are reimbursed at the normal rate, except for Medicaid. It is a revenue source for entities serving high needs populations. Folks are worried once that revenue is cut, they won't have the resources to provide other services. It is something the board needs to account for. The board needs to ask what it means to implement an upper payment limit and how it goes through the supply chain as the board intends. **Lila Cummings** said a drug would be deemed unaffordable only after consultation with 340B providers during the affordability review stage. It is a requirement the board receive feedback on the potential impacts of an unaffordable drug on the safety net and 340B providers. The board would also have utilization data for a prescription drug under consideration for upper payment limit, asking who is utilizing that drug and where is that drug being provided. **Chair Patterson** said there are growing populations of unhoused or with unstable housing who need services so boards want to ensure they are not impacting them.

Dr. Rebecca Spain said Colorado is looking at an upper payment limit as the sole strategy and Maryland is looking at multiple options for controlling drug costs, which is more in line with what Oregon is doing. Is there a methodology for comparing these different approaches to see what might have the biggest bang for the buck? **Andrew York** said the Maryland board gives staff the ability to take a broad look and the reports show what legislators can do to reduce costs. Maryland continues to get legislation to address drug affordability and staff tries to make sure it all fits together, taking a broader view in recommending policies. **Lila Cummings** said Colorado has programs outside the state board of insurance working on the issue. There are many components to affordability, to make it more affordable to state budgets, to help with costs of drugs used by a small number of individuals, or the overall price. The board asks, "Would an upper payment limit address this affordability goal?" **Andrew York** some of those will be hard conversations, so the board should make sure it has a framework for each view. **Daniel Hartung** asked about the pricing reviews in Massachusetts and New York. **Andrew York** said the programs are New York Medicaid Drug Cap, https://www.health.ny.gov/health_care/medicaid/regulations/global_cap/general_faqs.htm, and Massachusetts Health Policy Commission, https://www.mass.gov/service-details/drug-pricing-review#:~:text=Massachusetts%20Health%20Policy%20Commission%20Drug%20Pricing%20Review%20The,unreasonable%20or%20excessive%20in%20relation%20to%20the%20value. **Dr. Richard Bruno** asked when Colorado was prohibited from using cost for quality indicators. **Lila Cummings** said it happened during the legislative process, with concerns about undervaluing life due to age or disability.

Presentation on Pharmacy Benefit Managers: **Cassie Soucy and Numi Griffith**, senior policy advisors for DCBS, discussed pharmacy benefit managers (PBMs) and insight into the pharmaceutical supply chain, along with the regulatory scheme for PBMs in Oregon. Pharmacy benefit managers are intermediaries between health insurers, pharmacies, wholesalers, and manufacturers. The presentation is located on Pages 56-71 of the agenda packet posted here: https://dfr.oregon.gov/pdab/Documents/20221019-PDAB-document-package.pdf

Dr. Rebecca Spain asked how much of a rebate gets passed to the insurer? **Cassie Soucy** said passing along a rebate is a contract decision made between the PBM and the health insurer. It is an area that lacks transparency. Medicaid has specific requirements for passing through rebates.

Amy Burns asked about the difference in the number of complaints, 20,000 in 2015 and seven in 2021. **Numi Griffith** said the complaints were submitted as a single form but related to 100 prescriptions. For 2021, most of the seven complaints were related to the same incident. There is an issue with the Division of Financial Regulation (DFR) communicating to pharmacies about the complaint option. Staff receives anecdotal reports of noncompliance but few submissions. **Amy Burns** said it might help increase the number of complaints the state received if the information was published. **Numi Griffith** said the information is available on the website.

Robert Judge asked if DCBS has looked into PBMs establishing separately owned companies that contract directly with manufacturers and pass through rebates to the PBM. Some PBMs claim they pass through 100 percent of the rebates but there is a lack of transparency. **Numi Griffith** said the state is not assessing this, but there is awareness. Oregon is participating in a national work group on PBM regulation.

Vice Chair Shelley Bailey said the challenges impacting independent pharmacies also impact small chain pharmacies. She participated in a workgroup related to House Bill 4005. The vice chair said pharmacies fear retaliation and more audits for reporting PBM violations. Related to Covid 19, pharmacies have been on the front end of providing care and vaccines, which decreases the time they have to submit a violation report. **Numi Griffith** said they have heard it is difficult for pharmacists to take time away from giving vaccines and helping patients to complete a violation complaint form. As far as the retaliation issue, they have heard that as well. However, there are extensive rules about how audits are to be conducted.

Update on Draft Reports: Steve Kooyman, PDAB project manager, updated the board on the draft report schedule shown on Pages 72-78 in the agenda packet: https://dfr.oregon.gov/pdab/Documents/20221019-PDAB-document-package.pdf. **Steve Kooyman** said the board will review draft reports on Nov. 16 and final reports on Dec. 14. He thanked board members for their time and contributions to the reports. **Vice Chair Shelley Bailey** asked when board members could send edits and feedback to staff and **Steve Kooyman** said board members could send them any time before Nov. 18.

Announcements: The board reviewed the 2023 board calendar:
https://dfr.oregon.gov/pdab/Documents/20221019-PDAB-document-package.pdf

Public Comment: The chair allocated three minutes for public comment. He called on the person who signed up in advance to speak, Dr. Richard Bruno, board member and physician at Central City Concern, who spoke to the board.

Adjournment: The meeting was adjourned at 11:38 am. Dr. Richard Bruno made the motion, and Vice Chair Shelley Bailey provided the second.

MOTION by Dr. Richard Bruno to adjourn the meeting.
Board Voice Vote
Yea: Richard Bruno, Amy Burns, Daniel Hartung, Shelley Bailey, Akil Patterson.
Nay: None.
Motion passed.

Oregon Prescription Drug Affordability Board

Oregon Drug Price Hearing

- 10 a.m. to 12:15 p.m., Thursday, Dec. 1, 2022.
- Virtual meeting on Zoom. No pre-registration required.
- Oregon Legislators will serve as moderators.
- Opportunities for public comment.

Hearing Highlights

- Report highlights of the prescription drug price data collected from manufacturers and insurance carriers.
- Recommendations for legislative changes regarding prescription drug prices.

Panel Presentations

- *Insulin prices*: panelists include insurance carriers, generic insulin manufacturer, consumer advocates, with a presentation about activities in other states.
- *Pharmaceutical supply chain and PBM rebate transparency*: panelists include pharmacy benefit managers, prescription drug manufacturers and wholesalers, an independent pharmacy owner.

zoom **http://dcbspage.org/RXDRUGPRICEHEARING2022**

Overpatented, Overpriced. Curbing Patent Abuse: Tackling the Root of the Drug Pricing Crisis

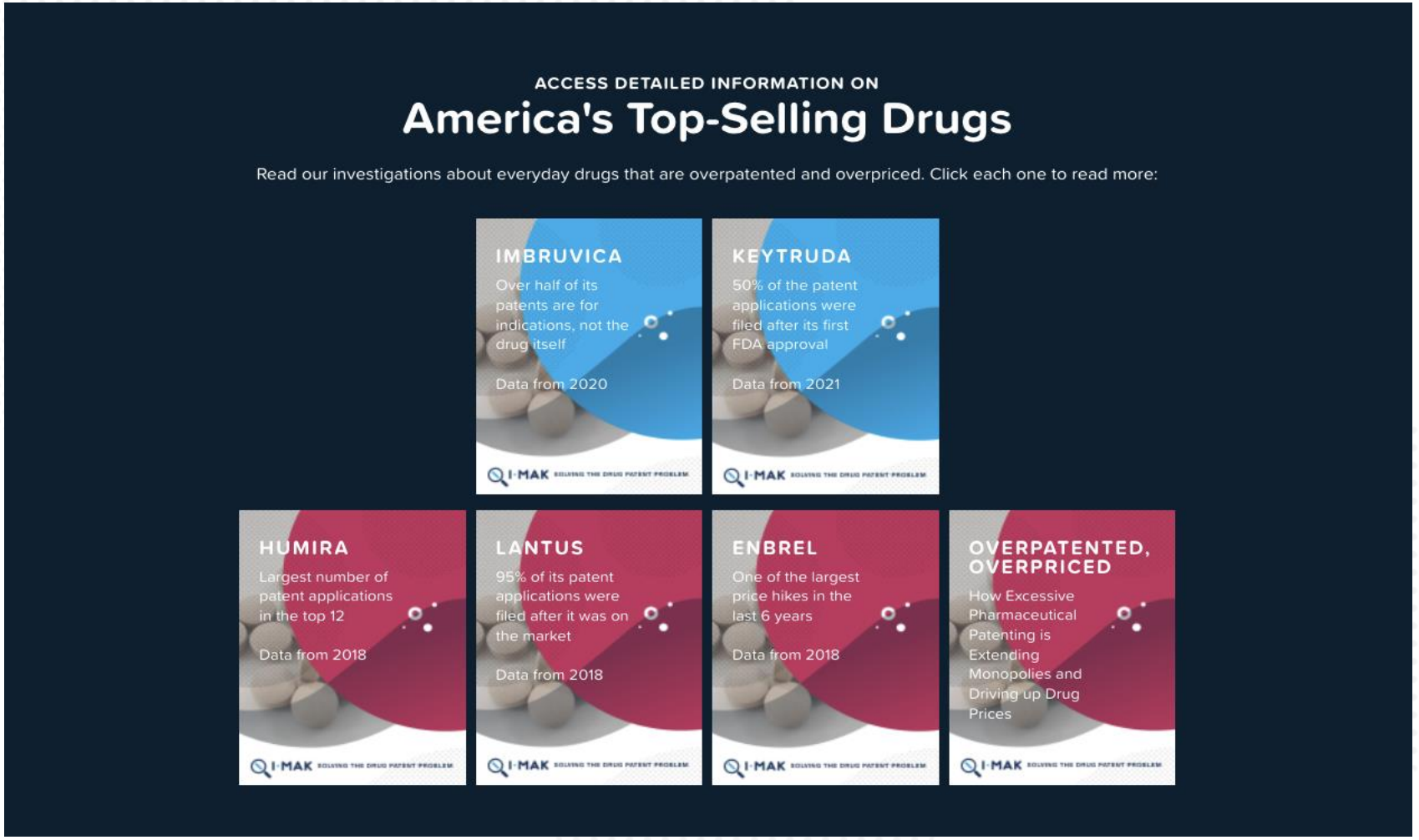
TAHIR AMIN

CO-FOUNDER/CO-EXECUTIVE DIRECTOR

16 NOVEMBER 2022

TWITTER: @REALTAHIRAMIN

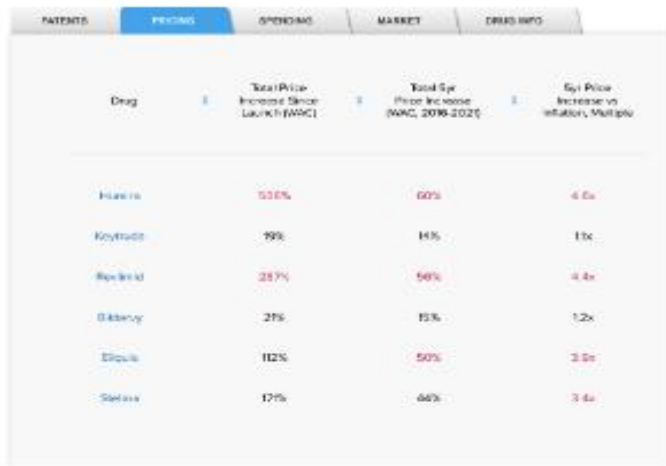
CURBING PATENT ABUSE: TACKLING THE ROOT OF THE DRUG PRICING CRISIS



CURBING PATENT ABUSE: TACKLING THE ROOT OF THE DRUG PRICING CRISIS

The Drug Patent Book Searchable Database

This database is user-friendly tool with comprehensive patent data on the ten top selling drugs



Top Selling Drugs Data Summary

A simple and easy resource that provides patent, pricing, spending, and market data for the ten top selling drugs in America.

Overpatented: 2022 Key Findings Report

Study highlights excessive patenting practices on blockbuster drugs, such as Revlimid, Humira and Enbrel, which impact cancer and arthritis.

KEY FINDINGS: TOP 10 SELLING DRUGS IN THE U.S IN 2021

KEY FINDINGS ON THE TEN TOP SELLING DRUGS

- On average, there are **74 granted patents on each of America's ten top selling drugs,** providing major drugmakers substantial advantage to keep generic and biosimilar competitors off the market.
- Drugmakers filed more than 140 patent applications on average per drug; on average **66% of patent applications were filed after the FDA approved the drug** to be on the market.
- Nearly one-third of Revlimid's cumulative sales in the U.S. have occurred after its primary patents expired, and **over two-thirds of Humira's U.S. sales have come after the expiration of its primary patents.**
- On average, **four times** as many patents are granted on the top ten drugs in the U.S. compared to Europe.
- Lower-cost generic and biosimilar versions of three top selling drugs - Humira, Eliquis, and Enbrel - launched in Europe an average of 7.7 years earlier than their expected U.S. entry. During this time, without generic or biosimilar competition Americans will spend an estimated **$167 Billion** on branded versions of just these three drugs. To date, these drugs still do not have generic or biosimilar competition in the U.S.

OVER HALF OF GRANTED PATENTS ARE FILED AFTER FDA APPROVAL

Condition(s) Treated ▾ | Drug Type ▾ | Orange/Purple Book ▾ | Patent Type ▾ | *Status* ▾

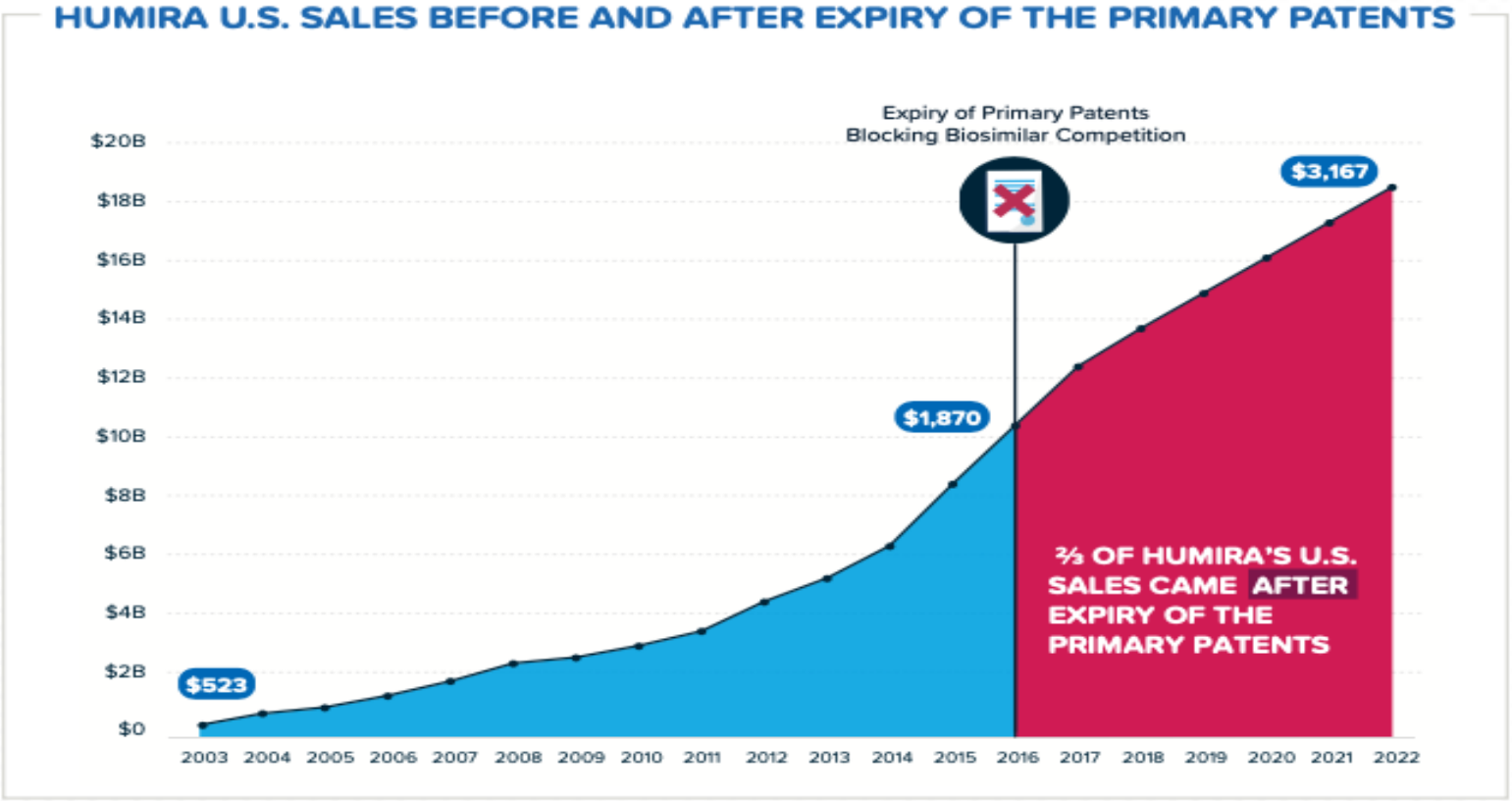
FDA Approval ▾

Drug	FDA Approval	After	Before	Totals
Biktarvy		11.4%	88.6%	100.0%
Eliquis		18.2%	81.8%	100.0%
Enbrel		78.4%	21.6%	100.0%
Eylea		58.2%	41.8%	100.0%
Humira		92.7%	7.3%	100.0%
Imbruvica		46.9%	53.1%	100.0%
Keytruda		41.0%	59.0%	100.0%
Revlimid		67.5%	32.5%	100.0%
Stelara		64.1%	35.9%	100.0%
Trulicity		73.3%	26.7%	100.0%
Totals		**62.8%**	**37.2%**	100.0%

*On average, 55% of granted patents are filed after FDA approval

** Biktarvy was recently approved in 2018, so we may see more patents still filed.

HUMIRA SALES BEFORE AND AFTER EXPIRY OF THE MAIN PATENT



The wholesale acquisition cost (WAC) price for Humira set by AbbVie was accessed at SSR Health and reported per unit of drug for three key years: at launch in 2003, when primary patents expired in 2016, and at present in 2022. U.S. sales of Humira were extracted from annual 10K SEC filings through 2021. For 2022, consensus estimates from Wall Street analysts were used and accessed via Bloomberg LP.

COMPARING DRUG PATENTS AND SPENDING IN THE U.S AND EUROPE

COMPARING DRUG PATENTS AND SPENDING IN THE U.S. AND EUROPE[9]

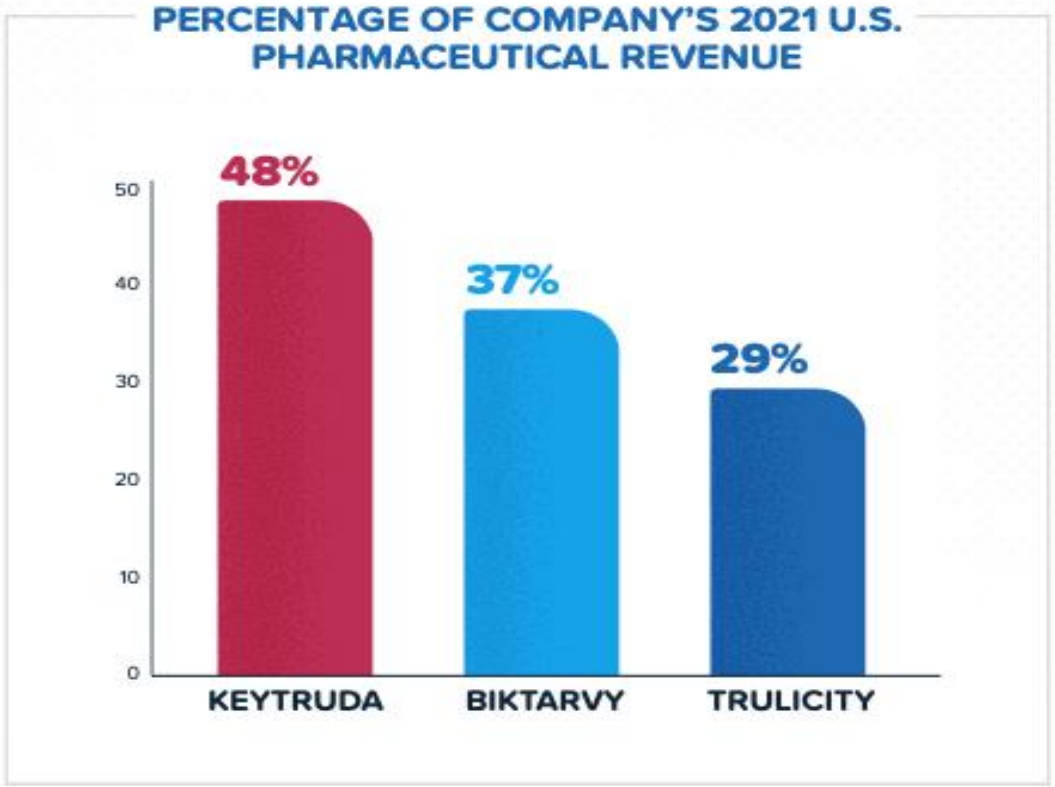
DRUG	PATENTS GRANTED IN U.S. VS E.U.	FIRST GENERIC / BIOSIMILAR ENTRY		YEARS OF EARLIER GENERIC/BIOSIMILAR ENTRY IN E.U.	TOTAL REVENUES IN THE U.S. AFTER GENERIC/BIOSIMILAR ENTRY IN E.U. (BILLIONS)
		E.U. MARKET	U.S. MARKET		
HUMIRA	6.4X	10-2018	1-2023	4.3	$68
ELIQUIS	2.4X	5-2022	4-2028	5.8	$48
ENBREL	4.1X	2-2016	4-2029	13.1	$52
TOTAL	--	--	--	23.2	$167
AVERAGE	4.3X	--	--	7.7	$56

PATENT AND MARKET HIGHLIGHTS FOR THREE TOP SELLING DRUGS IN THE U.S

PATENT AND MARKET HIGHLIGHTS FOR THREE TOP SELLING DRUGS

DRUG	ANNUAL U.S. SALES (2021, $ BILLIONS)	% OF CO.'S 2021 U.S. PHARMA REVENUE	YEARS ON MARKET (FIRST FDA APPROVAL DATE)	# PATENT APPLICATIONS	% PATENT APPLICATIONS FILED AFTER FDA APPROVAL	# OF GRANTED PATENTS
HUMIRA	$17.3	40%	19.7 (12/2002)	311	94%	165
REVLIMID	$8.7	30%	16.7 (12/2005)	206	74%	117
EYLEA	$5.8	48%	10.8 (11/2011)	134	65%	91
AVERAGE	$10.6	39%	15.5	217	78%	124

LOOKING FORWARD: PERCENTAGE OF COMPANY'S 2021 U.S REVENUE



Pharmaceutical revenue derived from a single drug, as reported in 202110K SEC filings by the companies.

PATENT THICKETS PAY

Each day of patent exclusivity can mean tens of millions in profit for a single drug.

Revlimid: $23.8 million per day

Humira: $47.5 million per day

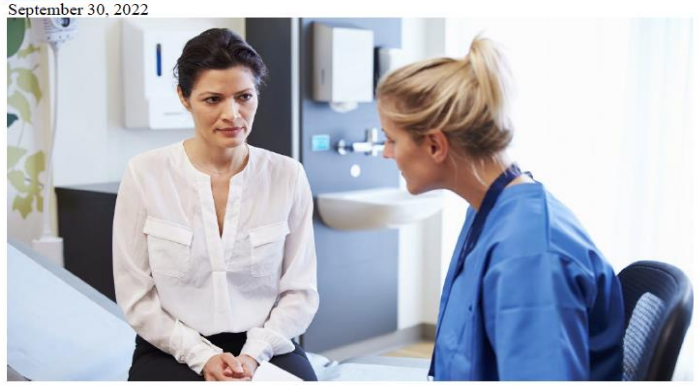
Keytruda: $26.8 million per day

INDUSTRY RESPONSE

PhRMA
RESEARCH • PROGRESS • HOPE

New report ignores benefits of patent system to innovation and patients

Megan Van Etten
September 30, 2022



A recent report from the Initiative for Medicines, Access & Knowledge – known as I-MAK – highlights fundamental misunderstandings about America's patent system and how it benefits patients and medical innovation. I-MAK accuses biopharmaceutical companies of blocking competition and gaming the system by patenting new innovations, when in reality, new patents do not extend old patents, and they do not prevent competitors from launching new products.

Furthermore, America's intellectual property (IP) system paves the way for generic and biosimilar competition. Here are a few key facts:

- Today, more than 90% of prescriptions for drugs are filled with generics, up from just 19% 35 years ago.
- A recent analysis showed that while patents protect new innovations for 20 years, the average time to market for generic competitors is only 13 years from when the brand medicine was launched.
- As of June 2022 there were 22 biosimilars launched against 7 innovator biologic medicines in the U.S. driving competition in oncology, supportive care and immunology, with projected savings from biosimilars to total over $100 billion by 2024.

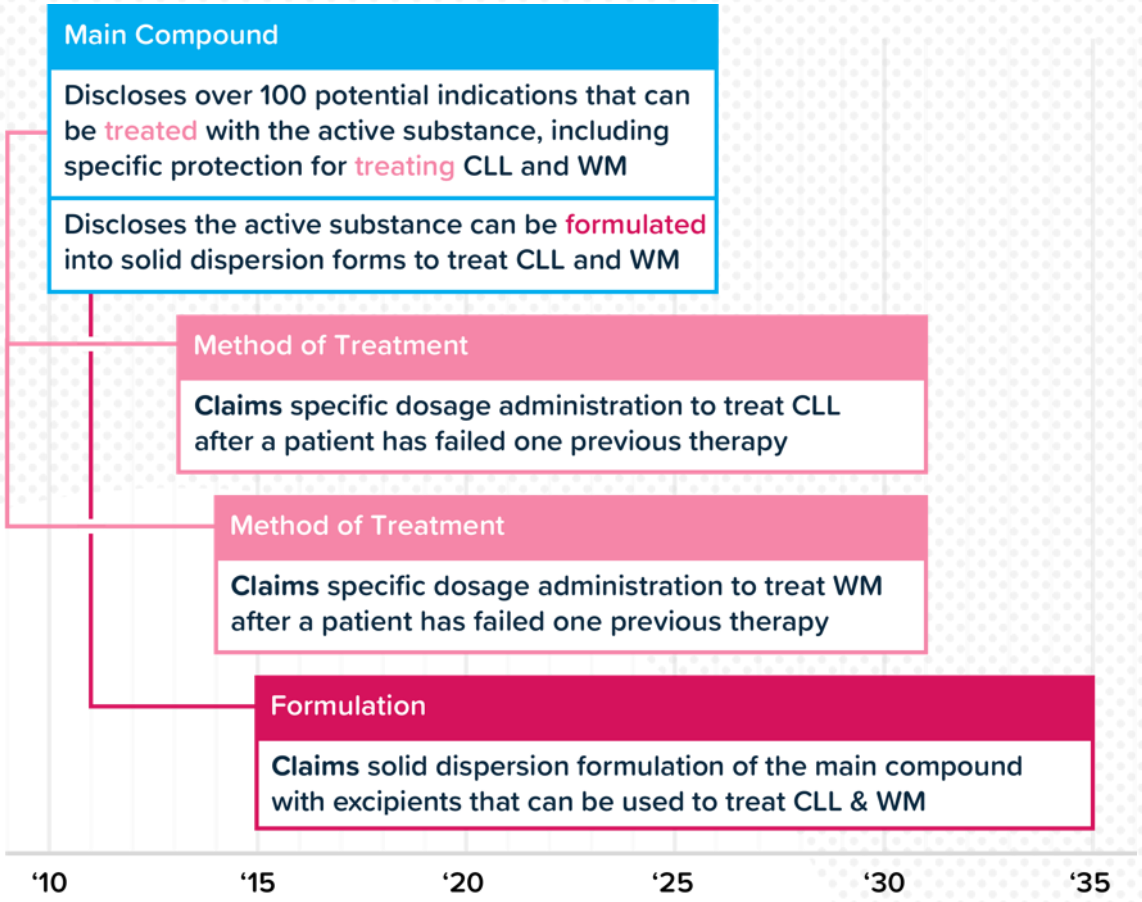
I-MAK's report ignores the fact that for a new patent to be granted, the request must be for something new and non-obvious. In the biopharmaceutical space, that can include finding a new dosage form, a new way to administer a medicine to patients or even an entirely new disease or population a medicine can treat.

This research and development that happens after FDA approval, often including costly and labor-intensive clinical trials, paves the way for important advances in patient care. The majority of cancer R&D is done after FDA approval. Nearly 60% of oncology medicines approved a decade ago received additional indications for other types of cancer. Doctors would not have known those medicines worked for more patients without the critical R&D that happened after the products were approved.

Intellectual property (IP) protections, including patents, incentivize manufacturers to continue working to improve their FDA-approved medicines. Progress is a good thing, and should be encouraged, not attacked.

We know there is work to be done to build a better health care system for patients, and it can be achieved without gutting critical incentives for innovation. The biopharmaceutical sector supports common sense solutions that would lower out-of-pocket costs that don't undermine future treatments and cures. We are eager to work with the Biden Administration to pursue policies that protect access, choice and innovation.

HOW COMPANIES BUILD A PATENT THICKET AND ARE THESE LATER PATENTS REALLY NEW AND NON-OBVIOUS INVENTIONS?

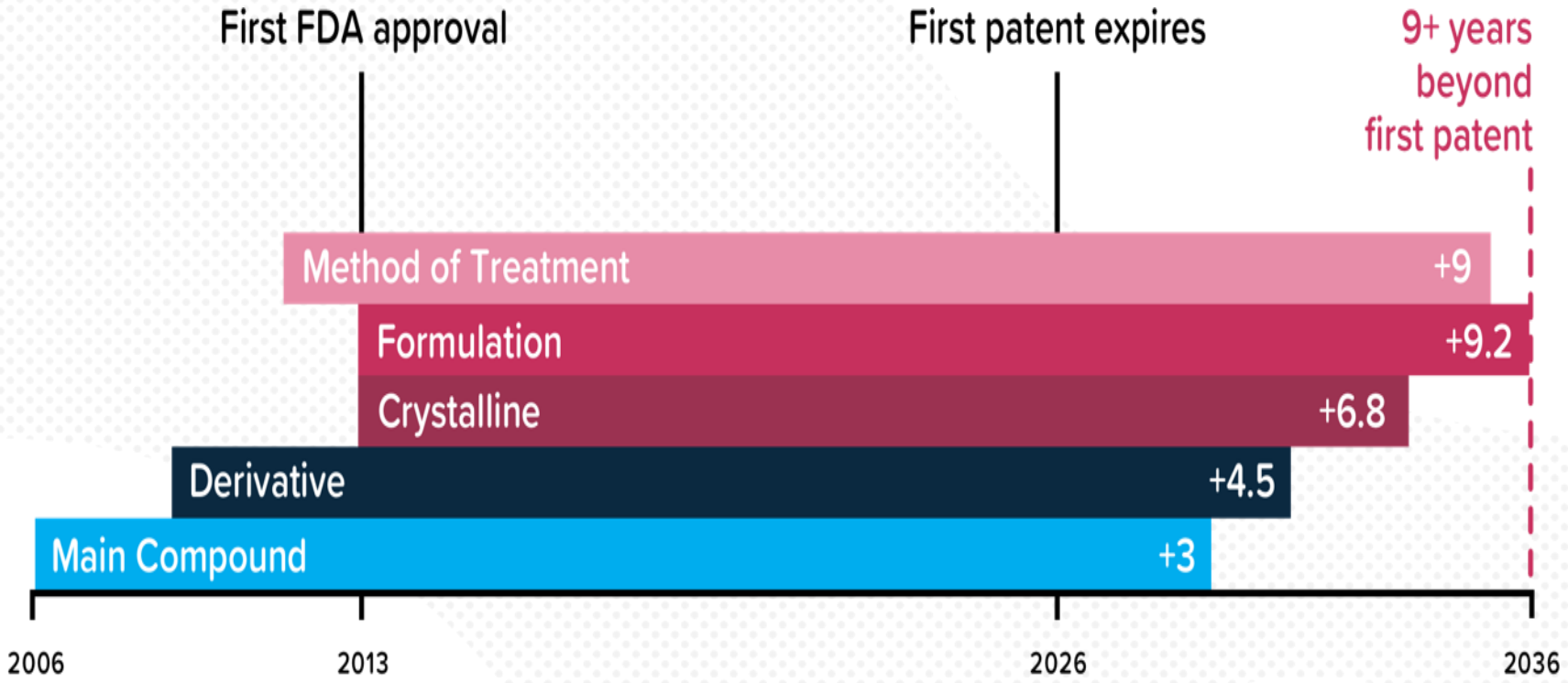


WM = Waldenstrom macroglobulinemia. **CLL** = Chronic lymphocytic leukemia.

Knowledge that is broadly disclosed in early patent applications is defined ever more narrowly and specifically in a spread of subsequent patent applications.

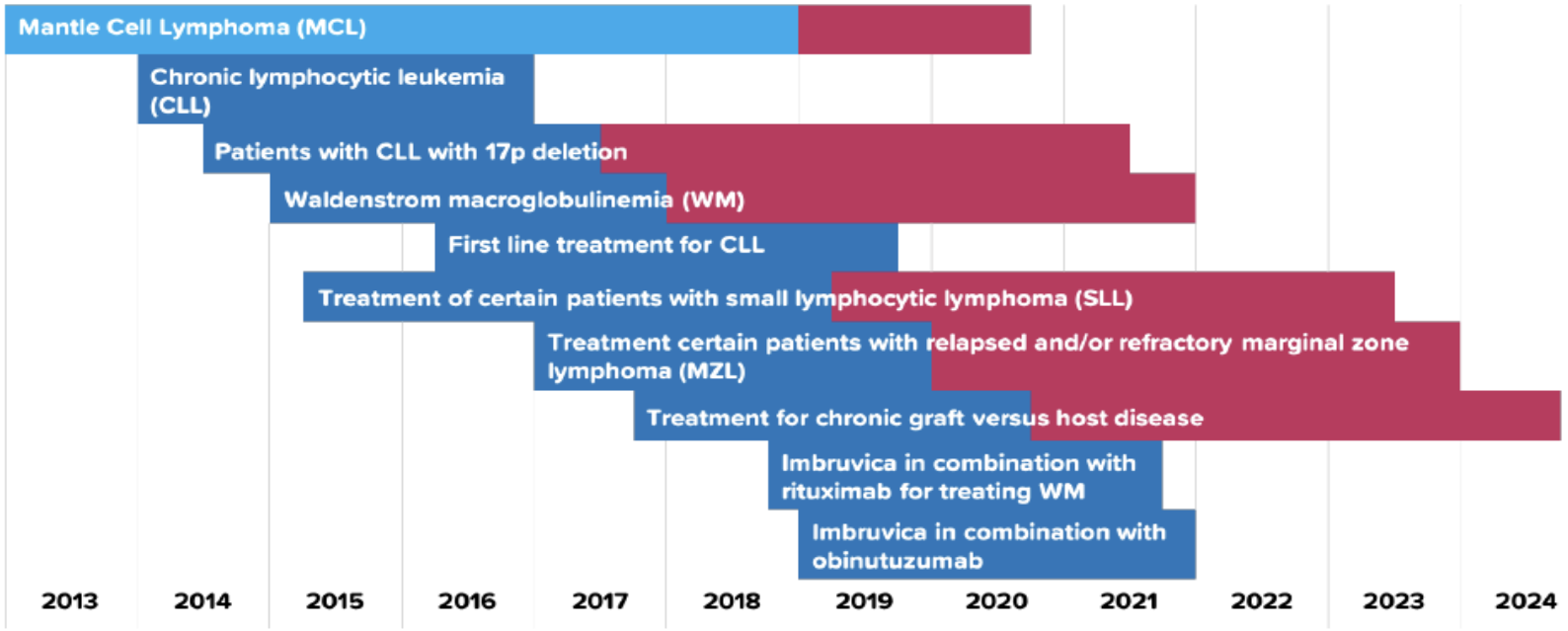
We have termed this “Drip-feeding patents”.

INDICATIONS AND FORMULATIONS LENGTHEN IMBRUVICA'S MONOPOLY TERM BY 9+ YEARS



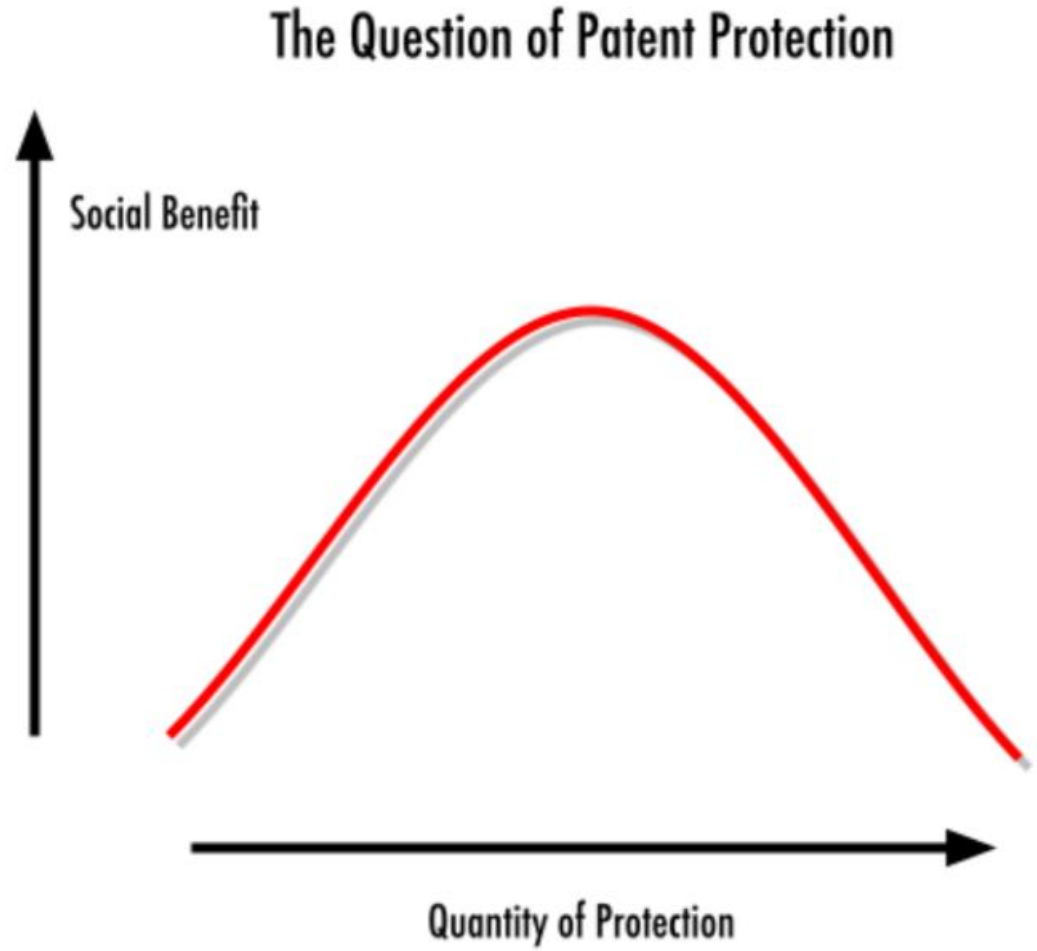
*Based on granted patents identified as of November 2019. I-MAK model of estimated revenue/spending for Imbruvica in the ten-year period from 2027-2036. Assumes total U.S. revenue for Imbruvica increases until 2024 when it reaches a peak of $8.7B ($6.2B AbbVie and $2.5B J&J), which is consistent with various market forecasts (see EvaluatePharma, May 2019). From 2025 onward, the model conservatively assumes there are *decreases* of 10% annually in total U.S. revenue/spending through 2036, based on new products entering the market and reduced market share for Imbruvica. There is no assumption of a generic product entering the market in this time period.

NON-PATENT INCENTIVES AND EXCLUSIVITIES FOR FOLLOW ON INDICATIONS (IMBRUVICA)



SOLUTIONS TO CURB PATENT ABUSE TO ALLOW FOR EARLIER ENTRY OF COMPETITION

- Raise the bar for what gets patented (including sharing materials between the FDA and USPTO for examination)
- Limit the number of times companies can to keep filing the same application after rejection
- End the patent office practice of terminal disclaimers that contribute to patent thickets
- Make it easier to challenge patents


The Question of Patent Protection
Social Benefit
Quantity of Protection

Oregon Prescription Drug Affordability Board

The Prescription Drug Distribution and Payment System:

Understanding the complex process of getting medications from the factory to the patients

A Report for the Oregon Legislature
December X, 2022

Oregon Prescription Drug Affordability Board

Board Members

Akil Patterson, Chair
Shelley Bailey, Vice Chair
Dr. Richard Bruno
Dr. Amy Burns
Dr. Daniel Hartung
Robert Judge
John Murray
Dr. Rebecca Spain

For more information, please contact:

Ralph Magrish
Executive Director

Cortnee Whitlock
Program and Policy Analyst

Prescription Drug Affordability Board
350 Winter Street NE
Salem, OR 97309-0405
971-374-3724
pdab@dcbs.oregon.gov
dfr.oregon.gov/pdab

Table of Contents

Introduction and background

The Oregon Legislature created The Prescription Drug Affordability Board in 2021 and directed the board to study the distribution and payment system of prescription drugs in Oregon. In this report, the Prescription Drug Affordability Board considers the complexity of how drugs move from the factory to the patient and how that process impacts the costs of prescription medications. The report highlights the prescription drug supply chains for Medicare, Medicaid, and employer-sponsored health insurance, and takes a closer look at impacts on patients and prescribers, including a look at underserved and disadvantaged populations. The report also reviews policies in other states and countries that potentially lower the cost of prescription drugs before examining reverse auction marketplaces and consolidated drug purchasing and payor negotiations for Oregon and local governments.

Through Senate Bill 844 (2021), the Oregon Legislature tasked the Prescription Drug Affordability Board to compile a list of nine prescription drugs and one insulin product for an affordability review. The board will work with the Prescription Drug Price Transparency program to prepare these drug affordability reviews for the legislature in 2023.

Growing Rx cost in the United States

The growing cost of prescription medication in the United States exceeds all other countries. Other countries spend an average of $550 annually on prescription medications, with the US averaging 2.56 times those in other nations.[1] Between 2008 to 2021, the median launch price for new drugs increased by over 8,000% from $2,115 to $180,087.[2] During this period, the average list price for new to market drugs increased by more than 20% a year, which was more than ten times the average rate of inflation. Projections are that prescription drug spending will increase in the coming years in part due to faster price growth.[3] The 2020 prescription drug spending growth increased by three percent to $348 billion, which was a slower rate than in

[1] Mulcahy, Andrew W., Christopher M. Whaley, Mahlet Gizaw, Daniel Schwam, Nathaniel Edenfield, and Alejandro Uriel Becerra-Ornelas. "International Prescription Drug Price Comparisons: Current Empirical Estimates and Comparisons with Previous Studies." RAND Corporation, RR-2956-ASPEC., 2021. https://www.rand.org/pubs/research_reports/RR2956.html. Accessed Nov. 4, 2022.

[2] Porter, Rep. Katie. "Skyrocketing: How Big Pharma Exploits Launch Prices to Cash in on Cancer." Office of US Representative Katie Porter. Nov. 2, 2022. https://porter.house.gov/uploadedfiles/skyrocketing_-_how_big_pharma_exploits_launch_prices_to_cash_in_on_cancer.pdf. Accessed Nov. 9, 2022.

[3] "National Health Expenditure Projections 2021-2030: Forecast Summary." Centers for Medicare & Medicaid Services. https://www.cms.gov/files/document/nhe-projections-forecast-summary.pdf. Accessed Nov. 9, 2022.

2019 due to "slower overall utilization and an increased use of coupons."[4] Between 2017 and 2021, self-administered cancer drugs had an inflation-adjusted launch price increase of 25.8%.[5]

As reported by the US Department of Health and Human Services, Assistant Secretary for Planning and Evaluation, the average price increase in January 2022 was approximately $150, and in July 2022 it was $250, with both increases more extensive than the same months in previous years. Also, in 2022, several drugs had list price increases of more than $20,000 or by more than 500 percent.[6] It is projected that over 2023 and 2024, retail prescription drug spending will increase to 4.7 and 5.1 percent due to faster price growth and increased utilization.[7]

Prescription drug supply chain for Medicare

This year President Joe Biden signed into law the Inflation Reduction Act with one of its provisions to allow Medicare to negotiate the price of certain prescription drugs to decrease the costs enrollees will pay for their medications.[8] Starting in January 2023, Medicare enrollees will see caps on insulin and have zero out-of-pocket costs for vaccines covered under their Part D plans. In 2025, Medicare enrollees will have an annual out-of-pocket cap of $2,000 for prescription drugs.

Medicare is a federal program with Part D covering outpatient prescription drugs for people age 65 or older. There are two types of Part D plans available. There are the stand-alone plans, which only cover prescription drugs, and the Medicare Advantage plans, which cover prescription drugs and provide other Medicare benefits. Drug prices for each type of Medicare plan are determined by negotiations between plans (or their pharmacy benefit managers—PBMs) and manufacturers.

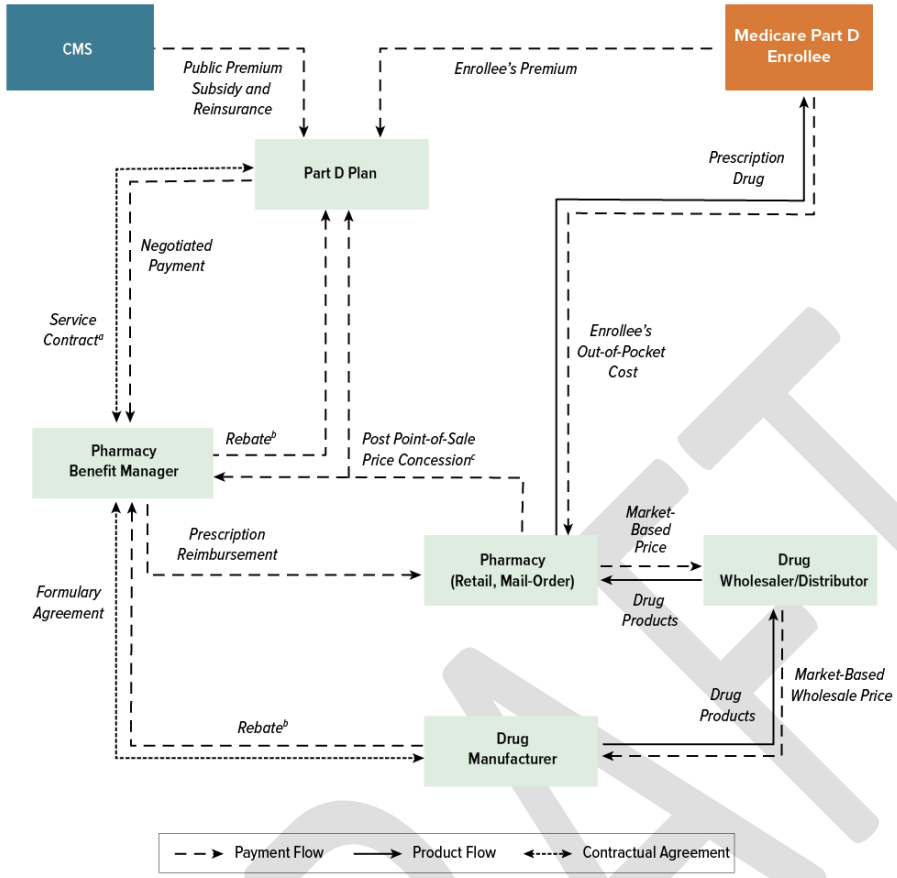
[4] "National Health Expenditures 2020 Highlights." Centers for Medicare & Medicaid Services. https://www.cms.gov/files/document/highlights.pdf. Accessed Nov. 9, 2022.
[5] Porter, Rep. Katie. "Skyrocketing: How Big Pharma Exploits Launch Prices to Cash in on Cancer." Office of US Representative Katie Porter. Nov. 2, 2022. https://porter.house.gov/uploadedfiles/skyrocketing_-_how_big_pharma_exploits_launch_prices_to_cash_in_on_cancer.pdf. Accessed Nov. 9, 2022.
[6] "HHS FY 2021 Budget in Brief: The Secretary Presents the FY 2021 Budget." U.S. Department of Health & Human Services. https://www.hhs.gov/about/budget/fy2021/index.html. Accessed Nov. 9, 2022.
[7] Skyrocketing-How Big Pharma Exploits Launch Prices to Cash in on Caner, Report by the Office of US Representative Katie Porter. Nov. 2022 viewable at; https://porter.house.gov/uploadedfiles/skyrocketing_-_how_big_pharma_exploits_launch_prices_to_cash_in_on_cancer.pdf
[8] "Fact Sheet: President Biden Takes Action to Lower Health Care and Prescription Drug Costs for Americans." The White House, Oct. 14, 2022. https://www.whitehouse.gov/briefing-room/statements-releases/2022/10/14/fact-sheet-president-biden-takes-action-to-lower-health-care-and-prescription-drug-costs-for-americans/. Accessed Nov. 4, 2022.

Figure 1 illustrates Medicare's purchasing system for outpatient prescription drugs. The Center for Medicare and Medicaid Services (CMS) provide subsidy and reinsurance into the Part D plan.[9] Additionally, the Medicare Part D enrollees pay a premium for the Part D plan and pay pharmacies any out-of-pocket cost for prescription medications. The Part D plan negotiates payments with PBMs, and the PBMs provide rebates negotiated with drug manufacturers. PMBs and manufacturers have formulary agreements that provide prescription reimbursement to the pharmacies. Manufacturers sell their products to drug wholesalers, who distribute them to pharmacies. Pharmacies pay post point of sale price concessions to pharmacy benefit managers for being part of the plan's preferred pharmacy network. This post point of sale compensation is called Direct and Indirect Remuneration (DIR) and is factored into the payments from CMS to Part D plans. DIR helps control Medicare program expenses and premiums but does not reduce the cost of medications at the point of sale for Plan D enrollees who receive their medications through a retail or mail-order pharmacy.

A 2016 analysis of per-member per-month (PMPM) DIR showed nearly a 14 percent per year increase between 2010 and 2015.[10] Increasing DIR levels means higher out-of-pocket spending for enrollees and increasing costs for the government.[11] Figure 2 provides a general overview of this trend.

[9] "A Comparison of Brand-Name Drug Prices Among Selected Federal Programs." Congressional Budget Office, February 2021. https://www.cbo.gov/publication/57007. Accessed Nov. 4, 2022.
[10] "Medicare Part D – Direct and Indirect Remuneration (DIR)." Centers for Medicare & Medicaid Services, Jan. 19, 2017. https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir. Accessed Nov. 4, 2022.
[11] Ibid.

Figure 1: Medicare Part D's system for purchasing brand-name outpatient prescription drugs.



Source: Congressional Budget Office, adapted from Kaiser Family Foundation, Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain (prepared by Health Strategies Consultancy, March 2005). https://www.kff.org/other/report/follow-the-pill-understanding-the-u-s/. Accessed Nov. 4, 2022.

Figure 2: DIR by payment years 2010 to 2015.

	2010	2011	2012	2013	2014	2015
Total DIR (Billions)	$8.7	$9.7	$10.5	$13.4	$17.4	$23.6
Gross Drug Costs (Billions)	$77.5	$84.8	$89.7	$103.6	$121.5	$137.4

Source: Analysis of DIR and enrollment data from the 2016 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplemental Medical Insurance Trust Funds (CY 2016 Medicare Trustee's Report) and cost data from PDE records. https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir. Accessed Nov. 4, 2022.

Prescription drug supply chain for Medicaid

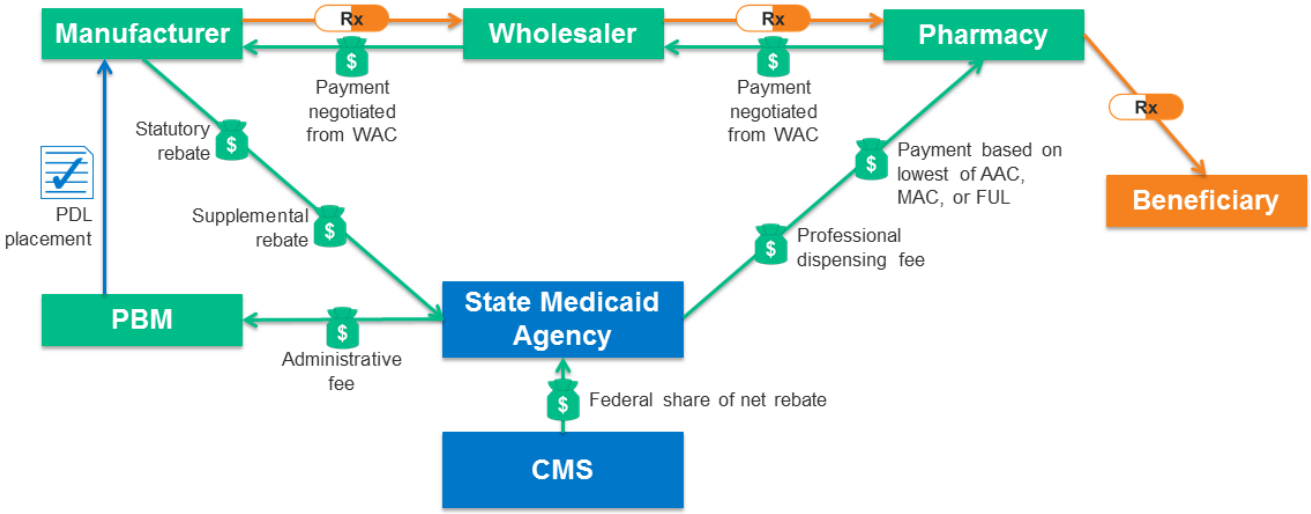
According to the Centers for Medicare & Medicaid Services (CMS), Medicaid is a joint Federal-State program that pays for medical assistance for individuals, families with low income and those with relatively few assets. Although pharmacy coverage is optional under federal Medicaid law, all states currently provide coverage for outpatient prescription drugs to all categorically eligible individuals and most other enrollees within their state Medicaid programs.[12] As of July 2022, Oregon has enrolled 1,331,443 individuals in Medicaid and CHIP (Children's Health Insurance Program) — a net increase of over 112% since 2013.[13] Oregon is one of 15 states that does not impose cost-sharing on beneficiaries for prescription drugs.[14]

In a 2020 Issues Brief, the Kaiser Family Foundation (KFF) looked at Medicaid's overall prescription drug prices, changes to federal rules in 2016, and the resulting reliance on pharmacy benefit managers and related impacts on state programs.[15] They found that the price Medicaid pays for drugs results from a complex set of factors and inputs, which KFF diagrams in Figure 3.

The KFF diagram illustrates a simplified version of Medicaid's payment and supply chain in a fee-for-service example. CMS makes its matching payment share, net of rebate, to the state Medicaid agency. State Medicaid programs then reimburse pharmacies for prescription drugs based on the ingredient costs for the drug and a dispensing fee for filling the prescription (*note that Medicaid agencies do not buy drugs directly from manufacturers, but rather, they reimburse retail pharmacies that fill prescriptions written for Medicaid enrollees)*. The amount the pharmacy receives is based on the drug's ingredient cost and professional dispensing fees paid by Medicaid, plus any cost-sharing paid by the beneficiary. For beneficiaries who receive their drug benefit through managed care organizations (MCOs), MCOs reimburse the pharmacy, typically through a PBM. MCOs in Oregon operate as Coordinated Care Organizations (CCOs).

[12] "Prescription Drugs." Centers for Medicare & Medicaid Services, U.S. Department of Health and Human Services. https://www.medicaid.gov/medicaid/prescription-drugs/index.html. Accessed Nov. 4, 2022.
[13] "Medicaid & CHIP in Oregon." Centers for Medicare & Medicaid Services, July 2022. https://www.medicaid.gov/state-overviews/stateprofile.html?state=Oregon. Accessed Nov. 4, 2022.
[14] "Medicaid Benefits: Prescription Drugs." Kaiser Family Foundation, 2018. https://www.kff.org/medicaid/state-indicator/prescription-drugs. Accessed Nov. 7, 2022.
[15] Dolan, Rachel and Tian, Marina. "Pricing and Payment for Medicaid Prescription Drugs." Henry J Kaiser Family Foundation, Issue Brief, January 2020. https://files.kff.org/attachment/Issue-Brief-Pricing-and-Payment-for-Medicaid-Prescription-Drugs. Accessed Nov. 4, 2022.

Figure 3: Distribution and payment system for Medicaid Prescription Drugs.



Source: "This figure is a simplified depiction of the payment and drug supply chain in the Medicaid prescription drug benefit provided through a fee-for-service setting. WAC is Wholesale "Acquisition Cost. While WAC is publicly available, the negotiated amount is not. AAC is Actual Acquisition Cost which can be based on a published schedule such as NADAC or determined through other benchmarks. MAC is the state Maximum Allowable Cost and FUL is the Federal Upper Limit, both programs establish ceilings for what Medicaid will pay for certain multiple-source drugs." Henry J. Kaiser Family Foundation. https://www.kff.org/wp-content/uploads/2020/01/9391-Figure-1.png. Accessed Nov. 4, 2022.

In Oregon, Actual Acquisition Cost (AAC) surveys and rate setting are managed by the Health Systems Division at Oregon Health Authority for fee-for-service pharmacy reimbursement. Pharmacies are reimbursed a professional dispensing fee for clinical pharmacy services rendered. It is tier structured based on the annual volume of prescriptions filled, ranging from $9.68 to $14.01. CCOs reimburse pharmacies for ingredient costs and dispensing fees through their contracted relationships with PBMs.

Some other states use the Maximum Allowable Cost (MAC) in reimbursement strategies in conjunction with the Federal Upper Limit (FUL). Both programs establish ceilings for what Medicaid will pay for certain multiple-source drugs.

State Medicaid agencies pay an administrative fee to pharmacy benefit managers to process claims for drugs, including those on the preferred drug list (PDL) for outpatient medicines that a state considers being the most cost-effective drugs. It is important to note that each state manages its Medicaid pharmacy program differently and that prescription drug coverage is an optional benefit under the CMS approved State Plan.

According to KFF, PDLs often include lower-cost drugs or drugs for which a manufacturer has provided supplemental rebates, as PDL placement is a primary lever that states use to negotiate supplemental rebate agreements. The manufacturer then provides the drugs to a wholesaler, who then delivers them to the pharmacy for a prescription to the beneficiary. Pharmacy payments are made by the pharmacy back to the wholesaler and then the manufacturer, and

these are based on the drug's wholesale acquisition costs or WAC. Oregon has a preferred drug list interactive database for providers to use when determining the most effective and safe drugs to prescribe to patients on the state's Medicaid fee-for-service program, Oregon Health Plan (OHP). The database is not a statewide PDL. In Oregon, non-preferred physical health drugs, e.g., those not on the PDL, are subject to prior authorization, whereas non-preferred mental health drugs do not require it. In developing the PDL, Oregon researchers and experts carefully consider the comparative safety and effectiveness of drugs recommended for placement on the PDL. Of those, only drugs representing the best value to OHP are added to the PDL. Best value is derived from several market factors, including supplemental rebates paid by brand manufacturers for their product's placement on the PDL. Each Coordinate Care Organization in Oregon sets its own list of preferred physical health drugs, and mental health drugs are carved out of CCO contracts and paid through the fee-for-service program.

Prescription drug supply chain for employer-sponsored health insurance

Similar to the Medicare and Medicaid distribution and payment systems, employer-sponsored health plans negotiate and distribute brand-name drugs through similar structures (Figure 4). However, instead of CMS funding a specific health plan, employers and beneficiaries pay premiums to contracted health plans and negotiate with PBMs on covered pharmacy costs. Pharmacies also negotiate the list price for drugs with wholesalers who distribute drugs produced by manufacturers. The AMP (average manufacturer price) is the average price paid to the manufacturer by wholesalers and retail community pharmacies that purchase drugs directly from the manufacturer. Drug manufacturers negotiate rebates with PBMs for product placement on their formularies to meet the needs of employer-sponsored benefit programs.

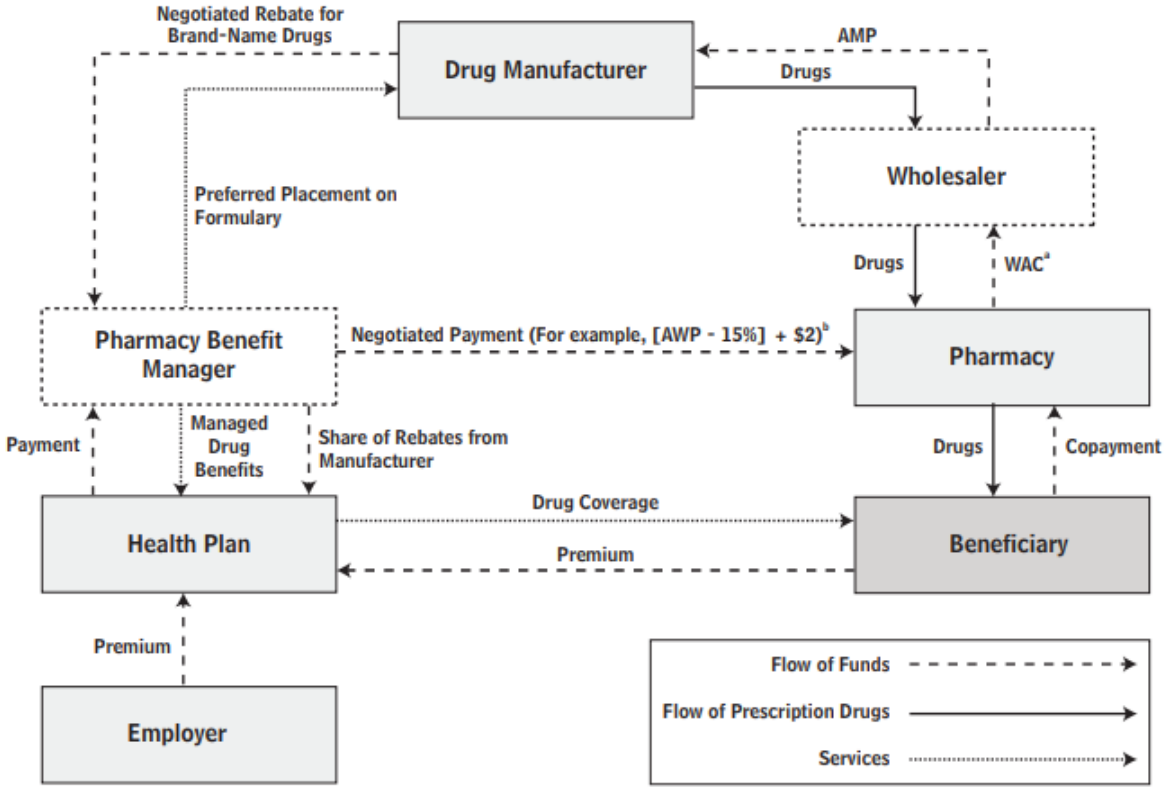
Although the distribution system seems straightforward, many components impact costs increases. For example, vertical integration of systems has resulted in large chain pharmacies often being the primary access point where patients fill their prescriptions. Only about one-third of pharmacies in the US are independent, making business viability difficult.[16] A recent report in the Harvard Journal on Legislation states, "the vertical integration of PBMs, insurers, and the rest of the healthcare delivery system increasingly presents opportunities to raise prices and increase profits."[17] The report also described a PBM billing a county jail $198.22 for a medication but only paid the independent pharmacy that serviced the jail $5.73 for the medication. The PBM made a $192.49 profit from the transaction, referred to as the "spread".

[16] "Competition, Consolidation, and Evolution in the Pharmacy Market." Controlling Health Care Costs, Issue Briefs, Aug. 12, 2021. https://www.commonwealthfund.org/publications/issue-briefs/2021/aug/competition-consolidation-evolution-pharmacy-market. Accessed Nov. 4, 2022.

[17] Carter, Rep. Earl L. Buddy. "Pulling Back the Curtain on PBMS: A Path Towards Affordable Prescription Drugs." Harvard Journal on Legislation, Vol. 59 2022, Pages 257-278. https://harvardjol.com/wp-content/uploads/sites/17/2022/06/201_Carter.pdf. Accessed Nov. 4, 2022.

It was reported that the independent pharmacy lost money due to the PBM, which managed the county's drug benefits plan.

Figure 4: Distribution and payment system for brand-name drugs for employer health insurance plan.



Source: Sood, Neeraj, PhD, Shih, Tiffany, Van Nuys, Karen, PhD, and Goldman, Dana, PhD. "Flow of Money Through the Pharmaceutical Distribution System." USC Leonard D. Schaeffer Center for Health Policy & Economics, Figure 1, June 6, 2017. https://healthpolicy.usc.edu/research/flow-of-money-through-the-pharmaceutical-distribution-system/.

340B pharmacy overview

The 340B program is named for Section 340B(a)(1) of the Public Health Services Act as amended in 1992. It is managed by the U.S. Health Resources & Services Administration (HRSA). It requires pharmaceutical manufacturers participating in the federal Medicaid Drug Rebate Program (MDRP) to sell outpatient drugs at discounted prices to qualified 340B entities, with discounts ranging from 25-50%. In 2020, estimated discounted drug purchases through the 340B program amounted to roughly 7 percent of the total U.S. drug market.[18] The program, as created by Congress, is intended to enable qualified or covered entities to stretch scarce federal

[18] "The Federal 340B Drug Pricing Program: What It Is, and Why It's Facing Legal Challenges." The Commonwealth Fund Explainer, Sept. 8, 2022. https://www.commonwealthfund.org/publications/explainer/2022/sep/federal-340b-drug-pricing-program-what-it-is-why-its-facing-legal-challenges. Accessed Nov. 8, 2022.

resources as far as possible, reaching more eligible patients and providing comprehensive services.[19] In the calendar year 2021, 340B-covered entities purchased $43.9 billion in outpatient drugs under the 340B Program, shown in figure 5.[20]

Figure 5: Aggregate 340B purchases by covered entity type

Entity Type	2021 Total Purchases
Disproportionate Share Hospitals	$34,288,472,705
Health Center Programs	$2,215,221,250
Children's Hospitals	$1,330,248,212
Rural Referral Centers	$1,174,151,155
Ryan White HIV/AIDS Program Part A	$1,151,719,110
Sexually Transmitted Disease Clinics	$871,036,833
Critical Access Hospitals	$620,923,559
Ryan White HIV/AIDS Program Part C	$519,299,391
Sole Community Hospitals	$451,594,319
Free-standing Cancer Centers	$304,098,033
Ryan White HIV/AIDS Program Part B	$234,735,497
Ryan White Part B AIDS Drug Assistance Program (ADAP) Direct Purchase Option	$230,807,198
Comprehensive Hemophilia Treatment Centers	$192,106,843
Federally Qualified Health Center Look-Alike Program	$173,025,319
Family Planning Clinics	$74,912,338
Ryan White HIV/AIDS Program Part D	$43,419,350
Tribal Contract/Compact with IHS (P.L. 93-638)	$30,973,328
Tuberculosis Clinics	$4,278,525
Urban Indian Hospitals	$1,154,612
Black Lung Clinics	$189,963
Ryan White Part B ADAP Rebate Option	$23,336
Native Hawaiian Heath Care Programs	$23,305
Total	**$43,912,414,182**

Source: 340B Prime Vendor Program, August 12, 2022. https://www.hrsa.gov/opa/updates/2021-340b-covered-entity-purchases. Accessed Nov. 8, 2022.

These safety net providers include Federally Qualified Health Centers (FQHCs), Rural Health Centers (RHCs), Tribal and urban Indian Health Centers (IHCs), Ryan White HIV/AIDS clinics, certain types of hospitals, including children's hospitals, Critical Access Hospitals, Disproportionate Share Hospitals, free-standing Cancer Hospitals, and sole Community

[19] "340B Drug Pricing Program Omnibus Guidance." Health Resources and Services Administration, Federal Register, vol. 80, 167, 52300-52324, Aug. 28, 2015. https://www.govinfo.gov/content/pkg/FR-2015-08-28/pdf/2015-21246.pdf. Accessed Nov. 8, 2022.

[20] "2021 340B Covered Entity Purchases." Health Resources & Services Administration, August, 2022. https://www.hrsa.gov/opa/updates/2021-340b-covered-entity-purchases. Accessed Nov. 8, 2022.

Hospitals. Also included are black lung clinics, hemophilia treatment centers, Title X Family Planning Clinics, and several other types of specialty clinics.

The 340B program has faced scrutiny for many years. In 2012, the Duke University Hospital reported five-year profits of $282 million accrued through its outpatient departments and affiliated clinics as a result of its participation in the 340B program.[21] 340B covered entities can generate profits by prescribing drugs to patients with private insurance or Medicare. 340B hospitals are not required to pass along their discounts to patients or insurers or to demonstrate their investments in outpatient programs for the poor. Consequently, these providers can generate 340B profits by pocketing the difference between the discounted price they paid for the drugs and the higher reimbursement paid by insurers and patients.[22]

For many years, criticism was centered around hospitals. In 2013, Senator Chuck Grassley noted the following:

> Hospitals can elect to sell all of their 340B drugs to only fully insured patients while not passing any of the deeply discounted prices to the most vulnerable, the uninsured. This is contrary to the purpose of the 340B program since much of the benefit of the discounted drugs flows to the covered entity rather than to the vulnerable patients that the program was designed to help.[23]

The program has been under recent scrutiny and legal challenges in more recent years around several requirements for program participation. Specifically, a covered entity may not seek 340B discount pricing on drugs provided to an individual who is not considered a "patient" of the covered entity.[24]

An individual is a patient of the covered entity, eligible for the benefits of 340B Program benefits only if:

- The covered entity has established a relationship with the individual such that the covered entity maintains records of the individual's healthcare; and
- The individuals receive health care services from a professional employed by or contracted with the covered entity; and

[21] Conti, Rena M, and Peter B Bach. "The 340B Drug Discount Program: Hospitals Generate Profits by Expanding to Reach More Affluent Communities." Health Affairs (Project Hope) vol. 33,10 (2014): 1786-92. doi:10.1377/hlthaff.2014.0540. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4591849/#R4. Accessed Nov. 8, 2022.
[22] Ibid.
[23] Ibid.
[24] "340B Drug Pricing Program Omnibus Guidance." Health Resources and Services Administration, Federal Register, vol. 80, 167, 52300-52324, Aug. 28, 2015. https://www.govinfo.gov/content/pkg/FR-2015-08-28/pdf/2015-21246.pdf. Accessed Nov. 8, 2022.

- The individual receives a health service from the covered entity, consistent with the grant funding provided to the covered entity.

Manufacturers have expressed concerns about the rapid rate of growth in the program from 8,100 provider sites in 2000 to 50,000 by 2020.[25] While some of this growth can be attributed to the passage of the Affordable Care Act (ACA) in 2010, which expanded the type and number of providers eligible for program participation, much attention has been garnered around the use of 340B contract pharmacies. Under HRSA guidelines, covered entities may dispense 340B drugs to patients through contract pharmacy arrangements and maintain responsibility for ensuring compliance with all program requirements. Contract pharmacies must carve-out Medicaid (i.e., not use 340B drugs for Medicaid patients) unless the covered entity has an arrangement with the state Medicaid agency to prevent duplicate discounts.[26] Some manufacturers have begun restricting contracting arrangements for enrolled providers to submit patient drug claims data to receive the discounted price. Since July 2020, at least sixteen drug manufacturers have said they will limit or halt discounts to safety net hospitals for drugs dispensed at community-based pharmacies.[27]

Providers state that any effort to limit the use of contract pharmacies violates 3430B statutes and HRSA guidance. The Biden administration has reviewed the measures drug manufacturers are imposing on providers and determined that their actions are in violation of the law, resulting in 340B entities paying more than the discounted price they are eligible to receive.[28]

Impact of the current prescription drug supply chain for patients and prescribers

Patients are commonly prescribed brand-name medication over generic drugs, further increasing costs. As direct-to-consumer and direct-to-prescriber marketing for high-cost drugs has increased, and there is limited marketing for generics manufacturers, patients are not always best positioned to understand that generic drugs are of equal therapeutic value. Given the use of copay assistance programs, the true cost to the system for the individual is often not known. Despite having FDA approval, some patients' reluctance to embrace generic drugs is

[25] "The Federal 340B Drug Pricing Program: What It Is, and Why It's Facing Legal Challenges." The Commonwealth Fund Explainer, Sept. 8, 2022. https://www.commonwealthfund.org/publications/explainer/2022/sep/federal-340b-drug-pricing-program-what-it-is-why-its-facing-legal-challenges. Accessed Nov. 8, 2022.
[26] "Contract Pharmacy Services." Health Resources & Services Administration, June 2022. https://www.hrsa.gov/opa/implementation-contract. Accessed Nov. 8, 2022.
[27] Carbajal, Erica. "16 Drugmakers Restricting 340B Discounts." Becker's Hospital Review, March 22, 2022. https://www.beckershospitalreview.com/pharmacy/16-drugmakers-restricting-340b-discounts.html. Accessed Nov. 8, 2022.
[28] "The Federal 340B Drug Pricing Program: What It Is, and Why It's Facing Legal Challenges." The Commonwealth Fund Explainer, Sept. 8, 2022. https://www.commonwealthfund.org/publications/explainer/2022/sep/federal-340b-drug-pricing-program-what-it-is-why-its-facing-legal-challenges. Accessed Nov. 8, 2022.

compounded by insurance companies formularies or preferred drug lists. The appearance to patients that insurance companies choose to cover only selected medications and not cover prescriptions prescribed by their doctors adds to distrust when insurance companies substitute generics for brand-name medications.

Payers commonly use prior authorizations (PA) as a cost containment strategy, which is a mechanism that requires the payor's approval before the patient receives coverage for the drug prescription. Each payor has different requirements to meet approval, and this process can impact or delay patient care. According to a survey by the American Medical Association, 88% of the 1004 health professionals surveyed reported a high burden due to PA.[29] The average number of PA per week was 41, taking roughly 13 hours to complete. The same survey found that 93% of physicians reported PA causing a delay in care for their patients, with one-third of physicians saying the delays resulted in serious adversity, including hospitalization, disability, and death. Although indeterminate, cost associated with PA do have an impact on the prescription drug distribution and payment system.

A 2021 study by Howell et al. estimated that payors, manufacturers, physicians, and patients incur approximately $93.3 billion in costs annually on implementing, contesting, and navigating health care service delivery and payments.[30] Payors spend approximately $6.0 billion annually administering drug utilization management, and manufacturers spend approximately $24.8 billion supporting patient access in response. Physicians devote approximately $26.7 billion in time spent navigating health system requirements. Moreover, patients spend roughly $35.8 billion annually on drug cost-sharing, even after taking advantage of manufacturer and other sources of financial support.

Since many patients cannot afford their medications, manufacturers often offer a drug coupon as an option to use their brand-name drugs. These coupons make the drug less expensive (even free) to the individual but that cost is carried to other parts of the delivery system. Manufacturer coupons, also called copay coupons or copay assistance programs, can only be used for that manufacturer's medicine. However, many prescribing physicians and patients don't know if copay coupons are always available for the prescribed medication.

Patients with no or limited insurance can be referred to a patient assistance program (PAP). Pharmaceutical manufacturers sponsor a PAP to provide financial assistance for medications. The patient sometimes is required to show proof of qualified income to be in the program. Although the copay coupon and PAP are programs to help patients afford their medications,

[29] "2021 AMA Prior Authorization (PA) Physician Survey." American Medical Association, 2022. https://www.ama-assn.org/system/files/prior-authorization-survey.pdf. Accessed Nov. 4, 2022.
[30] Howell, Scott, Yin, Perry T., and Robinson, James C. "Quantifying The Economic Burden Of Drug Utilization Management On Payers, Manufacturers, Physicians, And Patients." Health Affairs (Project Hope) vol. 40,8 (2021): 1206-1214. doi:10.1377/hlthaff.2021.00036. https://pubmed.ncbi.nlm.nih.gov/34339243/. Accessed Nov. 7, 2022.

these programs do little to reduce the cost of prescriptions overall or make them affordable for the healthcare system.

Patients with Medicare cannot use copay coupons but can be directed to patient assistance programs. Qualifying and getting support can take weeks to months which may delay the start or lead to interruptions of medication risking worsening illness.

Due to high copays, high deductibles, and out-of-pocket costs, patients become discouraged in medication adherence. Although manufacturers offer coupons to patients to afford drugs, these coupons can have multiple effects that end up hurting patients. For example, coupons from drug manufacturers lower the branded costs to consumers to equal or even lower than the cost of equivalent generics, per a research summary by Leemore Dafny, Christopher Ody, and Matt Schmitt.[31] Researchers at Harvard and UCLA have found coupons for brand-name drugs facing generic completion boosted retail sales by more than 60% and increased spending between $30 million and $120 million per drug during the five-year study period. This translated to as much as $2.7 billion increase in spending for the 23 drugs they studied.[32] Insurance companies still pay the total price for the drug, which raises premiums for everyone. Branded drugs with coupons also experienced price growth of 12-13% per year vs. 7-8% for branded drugs without coupons.[33] Another adverse effect of manufacturer coupons is in many states, including Oregon, those coupons do not count toward the high out-of-pocket maximums that many patients have with their insurance.[34]

Non-profit pharmaceutical companies like Civica Rx might be able to lower list prices of drugs and sell directly to large purchasers like the US Veteran's Administration and hospital systems.[35] They would not eliminate the rebate system favored by health insurance companies and PBMs. However, they may cause enough market disruption to reduce the excessive profits of PBMs and insurance companies. Still, there is no requirement to pass along any savings to patients.

[31] Dafny, Leemore, Ody, Christopher, and Schmitt, Matt. "Prescription Drug Coupons Actually Increase Healthcare Spending by Billions." Kellogg School of Management at Northwestern University, Kellogg Insight, Oct. 3, 2017. https://insight.kellogg.northwestern.edu/article/prescription-drug-copay-coupons-hurt-generic-competition. Accessed Nov. 4, 2022.

[32] Ibid.

[33] Dafny, Leemore, Ody, Christopher, Schmitt, Matt. "When Discounts Raise Costs: The Effect of Copay Coupons on Generic Utilization." Harvard Business School, NBER, Kellogg School and UCLA Anderson School of Management, Oct. 4, 2016. https://www.hbs.edu/ris/Publication%20Files/DafnyOdySchmitt_CopayCoupons_32601e45-849b-4280-9992-2c3e03bc8cc4.pdf. Accessed Nov. 9, 2022.

[34] "Copayments Adjustment Programs." National Conference of State Legislatures, Nov. 1, 2022. https://www.ncsl.org/research/health/copayment-adjustment-programs.aspx. Accessed Nov. 4, 2022.

[35] Dredge, Carter, MHA, and Scholtes, Stefan, PhD. "The Health Care Utility Model: A Novel Approach to Doing Business." The New England Journal of Medicine Catalyst, July 8, 2021. https://catalyst.nejm.org/doi/full/10.1056/CAT.21.0189. Civica, 2022. https://civicarx.org/. Accessed Nov. 2022.

Impact on underserved and disadvantaged populations

Pharmacy reimbursement commonly delegated to pharmacy benefit managers on behalf of health plans, can create financial stress on local, independent pharmacies. Independent pharmacies are more likely to serve rural and inner-city communities that are already underserved by the healthcare system. In 2021, GoodRx identified eight Oregon counties where 100 percent of the population lives more than 15 minutes from the three closest pharmacies. Increased drug costs and the evolution of the pharmacy benefit manager role and changes in reimbursement strategies by PBMs has led to a loss of independent pharmacies in Oregon and most other states.[36] Concerns around PBM reimbursement to pharmacies started before PBMs were financially integrated with insurers, national pharmacy retail stores, and mail order programs. Many dealings to maximize drug profits have harmed independent pharmacies and much of the healthcare system. When independent pharmacies disappear, access to care in already underserved communities declines even further. There are about 50 towns in Oregon where the closest pharmacy is at least 15 miles away from town. Another view is that between 2003 and 2018, ten Oregon rural zip codes went from having one pharmacy to none, and six Oregon rural zip codes went from having more than one pharmacy to just one pharmacy.

The pharmacy benefit design of many public and private health plans can create or exacerbate medical debt in the underserved, even among people with insurance. Based on the complex issues and systems described in this report, people often struggle to pay for their prescriptions. Multiple monthly prescriptions or one or two expensive medications on a more infrequent basis can create financial challenges for some people. The level of financial stress depends on income, insurance status, other medical/healthcare costs, and routine living costs. In addition, the higher the cost of a drug, the higher the patient cost sharing can be depending on benefit design, further increasing debt or rates of non-adherence. Many Medicare Part D and employer plans apply coinsurance cost sharing for very high cost drugs – a percentage of the drug cost rather than a flat copay amount. Inaccessible medicines or a decline in housing or food stability resulting from allocating money to medicine rather than other basic needs can lead to exacerbated health conditions or new healthcare needs.

A Brookings Institution report notes that Black, Latino or Hispanic, American Indian, and Alaska Native people are less likely to have medical insurance, are more likely to go into medical debt, and suffer avoidable medical morbidity.[37] Often, households of color go without insurance and

[36] Nguyen, Amanda, PhD. "Mapping Healthcare Deserts: 80% of the Country Lacks Adequate Access to Healthcare." GoodRx Health, Sept. 9, 2021. https://www.goodrx.com/healthcare-access/research/healthcare-deserts-80-percent-of-country-lacks-adequate-healthcare-access. Accessed Nov. 8, 2022.

[37] Perry, Andre M., Crear-Perry, Joia, Romer, Carl, and Adjeiwaa-Manu, Nana. "The Racial Implications of Medical Debt: How Moving Toward Universal Health Care and Other Reforms Can Address Them." The Brookings Institution, Oct. 5, 2021. https://www.brookings.edu/research/the-racial-implications-of-medical-debt-how-moving-toward-universal-health-care-and-other-reforms-can-address-them/. Accessed Nov. 4, 2022.

are nearly twice as likely to hold medical debt than households with insurance (28% vs. 17%, respectively).[38] Understanding socioeconomic status, geographic access to healthcare services, and health insurance coverage will help reduce inequities in underserved and disadvantaged communities.

Policies in other states and countries to lower Rx

The US pays significantly more for prescription drugs than other industrialized countries.[39] According to the Organization for Economic Co-operation and Development (OECD), the US spent $1376 per capita on prescription drugs, more than twice the average across other OECD countries ($571).[40] Pharmaceutical spending in the US was 47% higher than in Germany, 70% higher than in Canada, 108% higher than in Australia, and 198% higher than in the UK. Aggregate pharmaceutical spending is a function of product mix, volume, and price. Although the US is an outlier with respect to net pharmaceutical spending, it is not appreciably higher in terms of overall prescribing.

A 2017 survey of older adults in 11 industrialized countries reported that 55% of older adults in the US used four or more prescription drugs compared to 47% in the UK, the next highest country.[41] The US also leads the world in generic drug utilization.[42] Thus, excess pharmaceutical spending in the US is primarily a function of higher prices.

Most industrialized countries have a centralized healthcare authority that makes healthcare financing and delivery vastly more efficient. Although the specific approach that nations use to purchase pharmaceuticals differ, most share a similar feature in that the healthcare authority sets prices or has broad authority to restrict coverage based on cost or value.[43] Summarized

[38] Ibid.

[39] Papanicolas, I., Woskie, L. R., and Jha, A. K. "Health Care Spending in the United States and Other High-Income Countries." Jama, 319(10), 1024-1039, March 13, 2018. doi:10.1001/jama.2018.1150. https://pubmed.ncbi.nlm.nih.gov/29536101/. Sarnak, D. O., Squires, D., Kuzmak, G., and Bishop, S. "Paying for Prescription Drugs Around the World: Why Is the U.S. an Outlier?" Issue Brief, Commonwealth Fund, 1-14, Oct. 1, 2017. https://pubmed.ncbi.nlm.nih.gov/28990747/. Accessed Nov. 7, 2022.

[40] OECD. Health at a Glance 2021. https://www.oecd.org/health/health-at-a-glance/. Accessed Nov. 7, 2022.

[41] Osborn, R., Doty, M. M., Moulds, D., Sarnak, D. O., & Shah, A. "Older Americans Were Sicker And Faced More Financial Barriers To Health Care Than Counterparts In Other Countries." Health Affairs (Millwood), 36(12), 2123-2132, Nov. 15, 2017. doi:10.1377/hlthaff.2017.1048. https://pubmed.ncbi.nlm.nih.gov/29140737/. Accessed Nov. 7, 2022.

[42] Papanicolas, I., Woskie, L. R., and Jha, A. K. "Health Care Spending in the United States and Other High-Income Countries." Jama, 319(10), 1024-1039, March 13, 2018. doi:10.1001/jama.2018.1150. https://pubmed.ncbi.nlm.nih.gov/29536101/. Accessed Nov. 7, 2022.

[43] Emanuel, E. J., Zhang, C., Glickman, A., Gudbranson, E., DiMagno, S. S. P., and Urwin, J. W. "Drug Reimbursement Regulation in 6 Peer Countries." JAMA Intern Medicine, Nov. 1, 2020. doi:10.1001/jamainternmed.2020.4793. https://pubmed.ncbi.nlm.nih.gov/32986082/. Rodwin, M. A. "Common Pharmaceutical Price and Cost Controls in the United Kingdom, France, and Germany: Lessons for the United States." International Journal of Health Services, 2021. 51(3), 379-391. doi:10.1177/0020731421996168. https://journals.sagepub.com/doi/10.1177/0020731421996168. Accessed Nov. 7, 2022.

below is a brief description of pharmaceutical reimbursement in four high-income industrialized nations similar to the US.

United Kingdom (UK): The National Health Service (NHS) provides healthcare in the UK. Reimbursement for pharmaceuticals within NHS is contingent on review and approval by the National Institute for Health and Care Excellence (NICE). NICE evaluates the clinical and cost-effectiveness of potential new drugs for drugs approved by the European Medicines and Healthcare Products Regulatory Agency. As part of its review, NICE quantifies the incremental cost-effectiveness ratios (ICER) to determine a drug's relative value. NICE uses ICER estimates in their coverage determination recommendations to NHS. If a drug's ICER exceeds NICE's ICER threshold ($39,000 per quality-adjusted life year), the manufacturer can lower the product's price to secure coverage.

Canada: Similar to the UK, Canada has a single, publicly funded, healthcare system (Health Canada).[44] However, outpatient pharmaceuticals are not included in the federal health insurance program and are covered by each individual province or territory, which defines its eligibility criteria, coverage, and reimbursement formulas. Provincial and territorial governments rely on health technology assessments processed through the Common Drug Review (CDR) to provide synthesizes of clinical and cost-effectiveness data along with recommendations for coverage. While individual drug plans are not required to follow CDR coverage recommendations, they do 90% of the time.[45] Drug pricing in Canada is also under the jurisdiction of the Patented Medicine Prices Review Board, which was instituted to regulate launch prices and moderate price increases over time.

Germany: Established in 1883, Germany has the oldest social health insurance system in the world, financed through a mandatory non-governmental sickness fund along with optional private insurance.[46] Similar to the UK, Germany relies on a formal evaluation of a new drug's value by the Institute for Quality and Efficiency in Health Care (IQWiG).[47] IQWiG synthesizes

[44] Clement, F. M., Harris, A., Li, J. J., Yong, K., Lee, K. M., & Manns, B. J. "Using Effectiveness and Cost-effectiveness to Make Drug Coverage Decisions: A Comparison of Britain, Australia, and Canada." JAMA, 302(13), 1437-1443. doi:10.1001/jama.2009.1409, 2009. https://pubmed.ncbi.nlm.nih.gov/19809025/. McMahon, M., Morgan, S., and Mitton, C. "The Common Drug Review: a NICE start for Canada?" 77(3), 339-351, 2006. doi:10.1016/j.healthpol.2005.08.006. https://www.sciencedirect.com/science/article/abs/pii/S0168851005002186. Accessed Nov. 7, 2022.

[45] Tierney, M., & Manns, B. "Optimizing the Use of Prescription Drugs in Canada Through the Common Drug Review." CMAJ, 178(4), 432-435, Feb. 12, 2008. doi:10.1503/cmaj.070713. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2228339/. Accessed Nov. 7, 2022.

[46] Busse, R., Blümel, M., Knieps, F., and Bärnighausen, T. "Statutory Health Insurance in Germany: a Health System Shaped by 135 Years of Solidarity, Self-Governance, and Competition." Lancet, 390(10097), 882-897, July 3, 2017. doi:10.1016/s0140-6736(17)31280-1. https://pubmed.ncbi.nlm.nih.gov/28684025/. Accessed Nov. 7, 2022.

[47] Stern, A. D., Pietrulla, F., Herr, A., Kesselheim, A. S., and Sarpatwari, A. "The Impact Of Price Regulation On The Availability Of New Drugs In Germany." Health Affairs (Millwood), 38(7), 1182-1187, July 2019. doi:10.1377/hlthaff.2018.05142. https://www.healthaffairs.org/doi/10.1377/hlthaff.2018.05142. Accessed Nov. 7, 2022.

evidence and assigns the new drugs into one of six benefit levels ranging from "major added benefit" to "less benefit than the appropriate comparator." This benefit determination serves as the basis for price negotiations within the non-governmental health insurance organization. The decision is sent to an arbitration board if the manufacturer and the health insurer cannot agree on the price. If IQWiG determines there is no additional benefit relative to existing therapies, then the new drug is reference priced to those therapies.

Australia: Australia has a single-payer federally funded healthcare system with prescription drug coverage provided to all citizens through the Pharmaceutical Benefits Scheme (PBS).[48] PBS coverage is determined by the Pharmaceutical Benefits Advisory Committee (PBAC), an independent body that considers effectiveness and cost-effectiveness relative to alternative therapies. Only drugs with positive recommendations by PBAC are considered for coverage by PBS. The government primarily sets pricing.[49] Reference pricing is employed for drugs determined to be clinically similar to existing therapies. For new drugs that are superior to existing therapies, pricing is typically based on cost-effectiveness estimates. Additionally, Australia has policies in place that automatically reduce prices after a set time period.

Reverse auction marketplace for Oregon

As state policymakers explore innovative approaches to lower the costs of prescription medications and achieve greater transparency with the services that PBMs provide, an increasing number of states have introduced procurements using Reverse Auctions, a procurement method introduced in the early 2000s when internet-based technology became available to support this process. This method seeks to transform the often opaque and undisclosed practices used by PBMs to set prescription drug prices and manufacturer rebates into a more open and competitive process. Through a Reverse Auction, PBMs compete with one another through multiple open bidding rounds for a state's business. Seven states have already acted to establish policies that will require the use of Reverse Auctions for their PBM services: New Jersey, New Hampshire, Maryland, Louisiana, Colorado, Minnesota, and Ohio.

A Reverse Auction is a competitive, online bidding process used by states to select a PBM to manage public employee prescription benefits. Reverse Auctions provide a transparent and dynamic marketplace where PBMs compete with one another on the basis of the cost of their proposals over multiple bidding rounds to win the procurement. Auctions typically begin with PBMs submitting an opening price in response to a competitive procurement. PBM proposals

[48] Clement, F. M., Harris, A., Li, J. J., Yong, K., Lee, K. M., and Manns, B. J. "Using Effectiveness and Cost-effectiveness to Make Drug Coverage Decisions: A Comparison of Britain, Australia, and Canada." JAMA, 302(13), 1437-1443. doi:10.1001/jama.2009.1409, 2009. https://pubmed.ncbi.nlm.nih.gov/19809025/. Accessed Nov. 7, 2022.

[49] Emanuel, E. J., Zhang, C., Glickman, A., Gudbranson, E., DiMagno, S. S. P., and Urwin, J. W. "Drug Reimbursement Regulation in 6 Peer Countries." JAMA Intern Med. doi:10.1001/jamainternmed.2020.4793, 2020. https://pubmed.ncbi.nlm.nih.gov/32986082/. Accessed Nov. 7, 2022.

are published to allow qualified bidders to counteroffer with lower prices during multiple rounds of bidding until a bid is accepted by the state.

States using Reverse Auctions claim additional savings over their standard procurements since PBMs compete through multiple rounds of procurement until the state selects a winner. These successive rounds of bidding lower costs to states that can amount to millions of dollars over a standard contract period.

While there is growing interest by states in this procurement strategy, some in the industry argue this option does not address the root issue with PBM procurements and pricing methods. Arguably Reverse Auctions do not necessarily lead to transparency or cost-containment for pharmacy expenses. Critics say Reverse Auctions fail to address the PBM practice of using variations in average wholesale price (AWP) to create a markup known as "spread," which is the difference between the price charged to states and the amount paid to pharmacies. Reverse Auctions do not address the need to bring greater alignment in having PBMs charge plan sponsors exactly what pharmacies are paid. This is an issue raised by retail pharmacies who claim that current PBM pricing practices hurt independent pharmacies, virtually putting independent pharmacies out of business and eliminating competition.

Arguments against Reverse Auctions extend to manufacturer rebates as well. Today, PBMs create and implement their own "formularies" to maximize revenues from manufacturer rebates which may not be not passed to states. Even though Reverse Auctions may create concessions from PBMs to pass along a greater share of monies that are received from manufacturers, opponents of Reverse Auctions argue that full and complete understanding of the ways in which PBMs secretly generate revenue from states, such as spread pricing and rebate schemes, will result in a reduction in drug spending. Further evaluation of the model is necessary to see if it is of value in Oregon based on the state's groundbreaking work with the Oregon Prescription Drug Program (OPDP), the Northwest Consortium, and Array Rx and its current business model.

Consolidated drug purchasing and payor negotiations for Oregon state and local governments

To control rising costs for medications many states have implemented or are exploring options that consolidate or enhance their purchasing power. These include options that support the purchase of prescription drugs in bulk for facilities like state correctional facilities, or enable state and local government health plan purchasers to join forces to increase their negotiating power. In general, these arrangements seek to consolidate in-state purchasing to increase the volume purchased under one contract, or expand market share by creating more uniformity between pharmacy benefit programs. These arrangements can take many forms, but they have a common goal: to use size to enhance bargaining clout and gain concessions on the net price that is paid for medications.

Consolidated drug purchasing arrangements can operate using either intrastate or interstate purchasing models. Intrastate models increase market leverage by aggregating the lives and prescription drug utilization of more than one state program, such as state and local employee groups, correctional institutions, or public health entities. Interstate models increase market leverage by aggregating the lives and prescription drug utilization of programs across multiple states. Either intrastate or interstate models can be further organized by whether participants are purchasers or payers.

A significant amount of work was done to explore bulk purchasing in 2019 prior to the pandemic. State and local government drug purchasers should reconvene to evaluate benefits and limitations of current membership in bulk purchasing pools and identify opportunities for alignment.

The following cite a couple of examples of each model:

Intrastate models:

1. **New Mexico's** Interagency Benefits Advisory Council (IBAC) is a joint purchasing collective established by state statute, and consists of Albuquerque Public Schools, New Mexico Public Schools Insurance Authority, New Mexico Retiree Health Care Authority, and the State of New Mexico's Risk Management Division (SONM). Among IBAC's initiatives to control escalating health care costs is a carve-out Pharmacy Benefit Manager program to oversee prescription drug costs for program participants. IBAC has administered a carve-out PBM program for these four state entities since 2002. The pharmacy benefit for each program that participates in IBAC is different, but they are all administered by a single PBM.

2. **Interagency collaboration**. Several states have a designated agency that coordinates the purchase of drugs to greater or lesser extents – particularly for state run-facilities.
    a. Washington state's Hep-C elimination subscription program contracts with a single manufacturer to supply Hep-C medications for the state, Medicaid, Public Employee, Public Health, and Corrections programs at a preferred price.
    b. Massachusetts established the State Office of Pharmacy Services (SOPS) in 1992, which standardized and consolidated multiple pharmacy care entities in a state to improve cost-effectiveness while retaining state oversight, control, and accountability.[50] SOPS administer the pharmacy services for almost 50 state facilities for the departments of Public Health, corrections, developmental services and mental health, sheriffs, and soldiers' homes. SOPS contracts with CompleteRx to operate the pharmacy services that include drug purchasing. This office also runs a

[50] State Office for Pharmacy Services. Commonwealth of Massachusetts, 2022. https://www.mass.gov/orgs/state-office-for-pharmacy-services.

naloxone purchasing and payer discount program for state offices and agencies, including law enforcement.

Like Massachusetts, other states have a designated agency that coordinates the direct purchase of drugs to greater or lesser extents – particularly for state run-facilities. Some state drug procurement agencies handle unified payor PBM contracting or manufacturer rebate negotiations. It is beyond the scope of this report to catalog all the different ways states assign prescription drug procurement responsibilities. Still, there is great variability in state drug procurement operations regarding both scopes of responsibilities and where the responsibility lies within the state government.

Interstate models:

1. **Medicaid supplemental rebate pools.** In addition to Medicaid Fee for Service rebates required under federal law, states can also negotiate supplemental rebate agreements with prescription drug manufacturers. States can negotiate rebate agreements with manufacturers on their own or can also join with other states to form purchasing pools.

   Three state Medicaid purchasing pools exist today, each with strengths and weaknesses. Pool administrators negotiate rebates for state Medicaid agencies that supplement the federally required rebates. States can select the pool or pools that make the most sense for their programs. The three pools include National Medicaid Pooling Initiative (NMPI), the Top Dollar Program (TOP$), and the Sovereign States Drug Consortium (SSDC). States agree to place supplemental rebate drugs on preferred status relative to drugs without supplemental rebates.

   Oregon participates in SSDC and was an early adopter of this state managed Medicaid rebate pool, joining in 2010. SSDC is unique among Medicaid rebate pools in that it is the only state administered pool approved by CMS.

2. **Multi-state group purchasing**. MMCAP Infuse operates out of the Minnesota Office of Procurement in the Department of Administration and has operated since 1985. The program is a purchasing cooperative that negotiates manufacturer and wholesaler on-invoice discounts for drug and medical supplies on behalf of thousands of governmental facilities and agencies in all 50 states. Minnesota state law limits MMCAP membership to non-profit entities with the authority to use their own state's procurement system. There is no membership fee; eligible entities register with MMCAP and pay service -- or purchase related administrative costs. Importantly, MMCAP represents purchasers. These entities and facilities buy and stock drugs for dispensing or administration. MMCAP does not deal in rebates on paid claims for government payer programs.

Oregon participates in MMCAP Infuse through contracts administered by the Department of Administrative Services. Oregon Department of Correction, Aids Drug Assistance Program and the Oregon Health Authority's immunization program each participate in contracts administered through the MMCAP Infuse Pharmacy Program which allows members access to a full line of brand and generic pharmaceuticals, including prescription and over-the-counter items.

3. **Multi-state prescription drug associations**. Oregon and Washington state legislatures established ArrayRx to develop prescription drug purchasing programs for public sector purchasers in 2006. Today, ArrayRx offers a suite of drug purchasing and management solutions, including Pharmacy Benefit Management (PBM) programs, Oregon's workers' compensation insurance (SAIF Corporation), prescription drug voucher services, Managed Medicaid pharmacy services, and state-sponsored prescription drug discount cards. ArrayRx is used by state public employee and state educator programs in Oregon and Washington, as well as SAIF, Washington Department of Corrections, Oregon State Hospital, various cities, a Medicaid Coordinated Care Organization (CCO), local hospital, and union groups. Most recently, the state of Nevada joined ArrayRx and will implement ArrayRx services for State programs. ArrayRx is unique in that it is open to private sector employer health plans.

Beyond inter- and intrastate bulk purchasing programs, states have also participated in targeted programs for select high-cost/high-spend products. Among these is the Vaccine for Children (VFC), a federal program operated on behalf of states that contracts with a single wholesaler to buy and store childhood vaccines for the Centers for Disease Control and Prevention (CDC) at CDC-negotiated prices.

Conclusion and recommendations

Glossary

AAC: Actual Acquisition Cost is the state Medicaid agency's determination of pharmacy providers' actual prices paid to acquire drug products marketed or sold by a specific manufacturer. AAC is the current Medicaid benchmark to set payment for drug ingredients.

AMP: Average Manufacturer Price is the average price paid to the manufacturer by wholesalers and retail community pharmacies that purchase drugs directly from the manufacturer. AMP is used to calculate drug rebates under the Medicaid Drug Rebate Program.

AWP: Average Wholesale Price is the published list price for a drug sold by wholesalers to retail pharmacies and nonretail providers. It is akin to a sticker price and used as a starting point for negotiation for payments to retail pharmacies.

Best Price: The lowest available price to any wholesaler, retailer, or provider, excluding certain government programs like the 340B drug pricing program and the health program for veterans.

EAC: Estimated Acquisition Cost is a benchmark previously used by many state Medicaid programs to set payment for drug ingredient cost.

FUL: The Federal Upper Limit sets a reimbursement limit for some generic drugs; calculated as 175% AMP.

MAC: Maximum Allowable Cost is a reimbursement limit set by states in addition to the FUL.

NADAC: The National Average Drug Acquisition Cost is intended to be a national average of the prices at which pharmacies purchase a prescription drug from manufacturers or wholesalers, including some rebates. NADAC can be used to calculate AAC.

PDL: Preferred Drug List

WAC: Wholesale Acquisition Cost is the manufacturer's list price to wholesalers. The WAC represents manufacturers' published catalog, or list, price for sales of a drug (brand-name or generic) to wholesalers. However, in practice, the WAC is not what wholesalers pay for drugs.

Oregon Prescription Drug Affordability Board

Generic Drugs:

How patents, shortages, contracts, and biosimilars impact the availability and cost of generic drugs

A Report for the Oregon Legislature
December X, 2022

Oregon Prescription Drug
Affordability Board

Board Members

Akil Patterson, Chair
Shelley Bailey, Vice Chair
Dr. Richard Bruno
Dr. Amy Burns
Dr. Daniel Hartung
Robert Judge
John Murray
Dr. Rebecca Spain

For more information, please contact:

Ralph Magrish
Executive Director

Cortnee Whitlock
Program and Policy Analyst

Prescription Drug Affordability Board
350 Winter Street NE
Salem, OR 97309-0405
971-374-3724
pdab@dcbs.oregon.gov
dfr.oregon.gov/pdab

Table of Contents

Introduction

The Oregon Legislature created the Prescription Drug Affordability Board in 2021 and directed the board to conduct a study on the operation of the US market for generic drugs, both dispensed by pharmacists and drugs administered by physicians. Requirements included a review of generic drug prices on a year-to-year basis; the degree to which generic drug prices affect insurance premiums as well as annual changes in health insurance cost sharing for generics; the potential for and history of generic drug shortages, and the degree to which generic prices affect annual spending for the Oregon Health Plan.

Background of generic drugs

Generic drugs play a crucial role in the United States (US) pharmaceutical market by providing patients with safe and effective therapies at a low cost. The term “generic” typically refers to small-molecule drugs that are synthesized through chemical processes. They are also called “multi-source” drugs because the same medications can be manufactured by multiple manufacturers. Regulated by the US Food and Drug Administration (FDA), generic drugs are formulated to have the same active ingredient, strength, dosage, and route of administration as the brand name “originator” medication. Additionally, generic medications are considered equivalent to branded products with respect to efficacy and safety.

The success of the US generic market is primarily attributed to the 1984 Drug Price Competition and Patent Term Restoration Act, or Hatch-Waxman Act, which established the foundation for today’s generic drug approval process. Generic drugs are approved through the Abbreviated New Drug Application (ANDA) regulatory pathway. The ANDA permits generic products to be approved with data supporting the drug’s bioequivalence, which entails submitting data that demonstrate the rate and amount of medicine absorbed, distributed, metabolized, and eliminated in the body is the same as that for the brand name drug.

Generic drug manufacturers are not required to submit clinical trial data to demonstrate efficacy. This substantially reduces the economic barriers to market entry and contributes to generics being less costly. Additionally, generic formulations for an approved brand name medication can be submitted for FDA approval after the market exclusivity and patent protection periods for the branded product expires.

Branded originator products are protected from generic competition through two mechanisms that can operate concurrently. The first is the market exclusivity periods granted by FDA upon approval. The second mechanism is patents, which are intellectual property protections issued by the US Patent and Trademark Office. Patents can be obtained throughout the product's life but typically only when the molecule is discovered.

Brand drugs have 20 years of patent protection from generic competition, which starts while a drug is still in development, and often years before it comes to market. When exclusivity and patent periods have expired (or are deemed to be invalid and subject to challenge), generic

manufacturers are permitted to submit an ANDA. As an incentive to bring generics to market and potentially challenge invalid patents, the first manufacturer to file the ANDA is granted a 180-day generic exclusivity period where no other manufacturers are allowed to market their approved generics.

Biologics and biosimilars are regulated through distinct approval processes. The FDA approves originator biologics through the Biologics Licensing Application (BLA) regulation under section 351(a) of the Federal Food, Drug, and Cosmetic Act, which is distinct from the small molecule drug pathway. Additionally, as part of the Affordable Care Act, the Biologics Price Competition and Innovation Act created a regulatory pathway for biologics analogous to the ANDA for small molecule generics, known as the BLA 351(k) pathway. This legislation created an abbreviated approval process for biological products that are demonstrated to be "highly similar" (biosimilar) to or "interchangeable" with an FDA-approved biological reference product. Biosimilar is a biological product that 1) is highly similar and 2) has no clinically meaningful differences relative to the reference biologic. An interchangeable biosimilar can be "expected to produce the same clinical results as the reference product in any given patient."[1] When administered more than once, the safety risk or efficacy of alternating between the biosimilar and reference product is not greater than the risk of using the reference product without such a switch.

Biologic medications and their non-originator analogs (biosimilars) are derived from living systems (e.g., bacteria cell lines) that are inherently more complex. Generics and biosimilars use landscape examples of biologics, including therapeutic proteins such as erythropoietin and insulin, monoclonal antibodies such as Adalimumab (Humira™), and vaccines. Unlike small molecule drugs, biologic drugs are complex molecules synthesized in living systems such as bacterial cell cultures.

The adoption of biosimilars in the US has been slower than in the rest of the world. In therapeutic areas where biosimilars have been launched, the average market share is about 65%. Only two biosimilars have an interchangeable designation in the US, meaning pharmacists can substitute a biosimilar for the reference product.

Generic drug pricing, cost, and utilization

Generic medications are cost-effective alternatives to brand-name medications. Generics represent more than 90% of all drugs dispensed annually in the US, but they only account for

[1] "Biosimilar and Interchangeable Products." U.S. Food & Drug Administration, Oct. 23, 2017, https://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products. Accessed on Nov. 1, 2022.

18% of total drug spending, and only 4% of overall healthcare costs.[2] When the market functions correctly, generics are priced 80% to 85% less than branded counterparts. Nine out of 10 prescription medications dispensed in the US are generic.[3] There are more than 16,000 generic medications available in the marketplace.

The passing of the Hatch-Waxman Act of 1994 resulted in a streamlined process for the FDA to approve prescription medications. The law balanced the market incentives to bring new patent-protected drugs to market with incentives to produce generics of those products once the patent expires.[4] This first generic product is priced less than the brand, but the actual price competition starts when three or more makers of the generic product compete for sales. Generic drugs are 95% less than the price of the brand name counterpart when there are more than six competing manufacturers of a particular generic drug.[5] Moreover, according to the Congressional Budget Office, spending on generic medications has fallen considerably as a percentage of total expenditures on health care services and supplies.

The exceptions to the rule of declining generic prices occur when:

1. There is only one generic manufacturer on the market (i.e., after a drug goes off patent, there is a single producer of generic medication for 180 days).
2. A shortage of raw materials drives up the cost of manufacturing or limits supply altogether.
3. When the market dynamics make manufacturing unprofitable for all manufacturers of the generic, in which case manufacturers exit the market and the generics often become costlier as a result.

Generic medications drive down prices for consumers, since multiple manufacturers (after the 180-day exclusivity period once a drug goes off patent) can compete to offer the same product.

The price set by manufacturers for generic medications is not the only determining factor in the net cost paid by patients and payors. The entity most responsible for determining what a drug will cost the payor and the patient is the payor's vendor -- the pharmacy benefit manager (PBM). PBMs are third-party companies that act as an intermediary between a payor (e.g.,

---

[2] Trish, Erin, PhD, Van Nuys, Karen, PhD, Popovian, Robert, PharmD. "U.S. Consumers Overpay for Generic Drugs: Policy Solutions must address the intermediaries who benefit." *USC Schaeffer*, May 2022. https://healthpolicy.usc.edu/research/u-s-consumers-overpay-for-generic-drugs/. Accessed Nov. 1, 2022.

[3] "Generic Drugs Undergo Rigorous FDA Review." U.S. Food & Drug Administration, Sept. 16, 2022, https://www.fda.gov/consumers/consumer-updates/generic-drugs-undergo-rigorous-fda-review. Accessed on Nov. 1, 2022.

[4] Drug Price Competition and Patent Term Restoration Act of 1984, S.2748, 98th Congress (1983-1984). https://www.congress.gov/bill/98th-congress/senate-bill/2748. Accessed on Nov. 1, 2022.

[5] Conrad, Ryan, PhD, Lutter, Randall, PhD. "Generic competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices." U.S. Food & Drug Administration, Dec. 2019. https://www.fda.gov/media/133509/download. Accessed on Nov. 1, 2022.

employer, health plan, government program, etc.,) and a pharmacy. The patient cost for generics is typically a small or moderate copay. The payor net cost is based on what the PBM reimburses the pharmacy for its cost to buy and dispense the generic to the patient. In addition to setting up pharmacy reimbursement and patient drug cost-sharing, PBMs negotiate rebates, create formularies, process claims, create pharmacy networks, provide drug utilization reviews, and provide mail-order and specialty pharmacy services.[6]

PBMs work with pharmacies on behalf of payors by creating a "network" of pharmacies, and each pharmacy has a contract with the PBM that describes how the pharmacy will be reimbursed. Generally, generic drug reimbursement for pharmacies is done using a formula that figures out the Maximum Allowable Cost (MAC) for each generic product. This number is the average that US pharmacies paid for that drug at some point in time, regardless of the specific manufacturer, and it incentivizes pharmacies to look for the lowest-cost product from wholesalers. This formula can, and does, disadvantage independent pharmacies that do not buy in the volume of chain stores. Chain store pricing goes into the MAC formula, so independents are reimbursed less than their costs.

Each PBM has its own methodology for MAC pricing, including how often to update it, what are the data sources used, and even which drugs are subject to it. Factors driving MAC reimbursement rates by PBMs in the market include how many manufacturers make the product, how long the generic drug has been generic, and how widely available the generic medication is (e.g., are there raw material shortages or product recalls).[7] Due to the ability of PBMs to set MAC pricing, PBMs have the most control over the ultimate cost of generic medications to the end payor and patient.

PBMs do not have to disclose to the payor (or the patient) what the PBM pays the pharmacies (e.g., the MAC rate for a generic drug) versus what the PBM is charging the payor to reimburse the PBM for payments to pharmacies. PBMs can and do charge the payor more than the PBM paid to pharmacies. Some State Attorneys General are looking into whether PBMs charged state entities more in pharmacy reimbursements than the PBM paid out to pharmacies (spread pricing). Medicaid PBMs have been found to be doing this in ten states so far. Some state legislatures are also starting to ban spread pricing, which will help small health plan payors that lack the market power to change the practice through contracting.

---

[6] "Pharmacy Benefit Managers." National Association of Insurance Commissioners, April 11, 2022. https://content.naic.org/cipr-topics/pharmacy-benefit-managers. Accessed Nov. 1, 2022.

[7] "Maximum Allowable Cost (MAC) Pricing." Academy of Managed Care Pharmacy, Oct. 28, 2021. https://www.amcp.org/policy-advocacy/policy-advocacy-focus-areas/where-we-stand-position-statements/maximum-allowable-cost-mac-pricing. Accessed Nov. 1, 2022.

Study of generic drugs

Americans spend, on average, $1,300 annually on prescription drugs—more than any other country in the world.[8] Due to the multiple influences on drug costs, as discussed above, small fluctuations and variances can lead to wide swings in generic prices year to year. One-off patent generic medications can vary widely in their manufacturing approaches and locations. Because of federal trademark law, each generic brand drug's size, shape, and color must look different.[9] These generic pills of the same medication can confuse consumers when the drug is refilled and the pharmacy stocks the product from another manufacturer.

Pay-for-delay agreements between generic and patent-holding pharmaceutical manufacturers cause delays when a generic comes to market competition among generic manufacturers and keep drug prices high. Estimates of the cost to consumers and the healthcare system of these deals run as high as $37 million per year.[10] The Federal Trade Commission has sued to stop numerous deals since 2010, and the Biden administration has proposed banning these practices.

Monopolistic market conditions also contribute to high drug prices when a manufacturer of a sole-source generic hikes the price of a drug (as was the case in 2015 with Turing Pharmaceuticals, then led by Martin Shkreli, raised the price of pyrimethamine from $13.50 to $750 per pill). These price hikes can lead to increased copays and premiums for the consumer.

A study from the Kaiser Family Foundation that included employer-sponsored health plan formulary design found that only 5% of workers in plans with three or more drug tiers had no cost-sharing for generic drugs. That figure was 6% for workers in plans with just two drug formulary tiers.[11]

There have been even more studies of Medicare Part D formularies. These plans were among the first to create multiple tiers for only generic drugs with different cost sharing for the tiers. A study done by Avalere looked only at generic coverage among Medicare Part D plans and found that generic drugs have been increasingly placed on higher cost-share tiers, including specialty

---

[8] Langreth, Robert. "Why Prescription Drug Prices in the US Are So High." Bloomberg, July 19, 2022. https://www.bloomberg.com/news/articles/2022-07-19/why-prescription-drug-prices-in-the-us-are-so-high-quicktake?leadSource=uverify%20wall. Accessed Nov. 1, 2022.

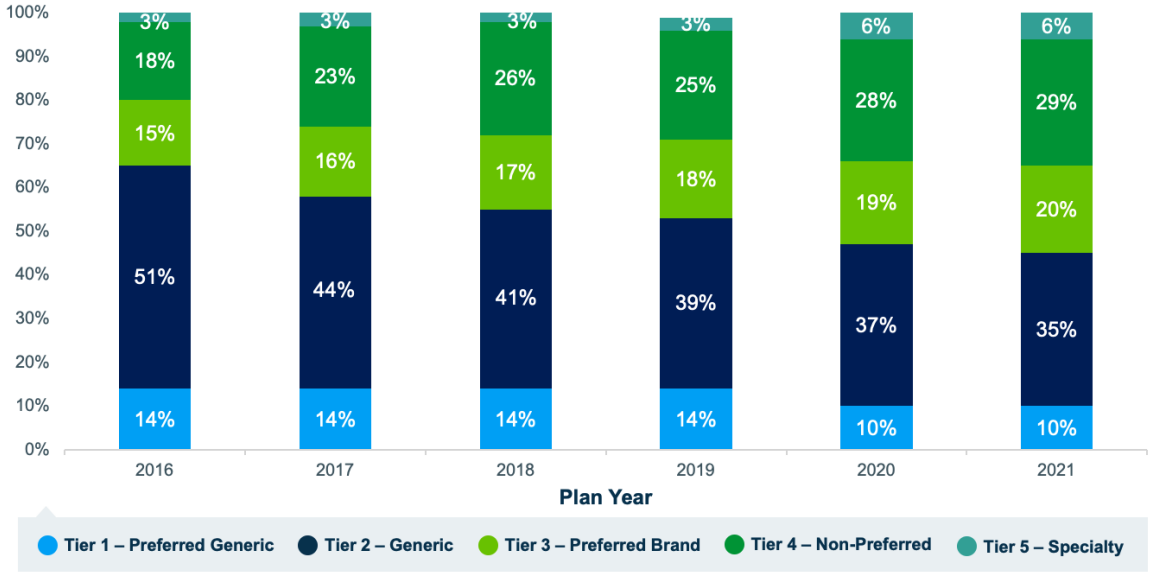
[9] "Generic Drugs: Questions & Answers." U.S. Food & Drug Administration, March 16, 2021. https://www.fda.gov/drugs/frequently-asked-questions-popular-topics/generic-drugs-questions-answers#q3. Accessed Nov. 1, 2022.

[10] Feldman, Robin. "The Price Tag of Pay-for-Delay." The Columbia Science & Technology Law Review, Volume XXIII, Fall 2021. https://journals.library.columbia.edu/index.php/stlr/article/view/9389/4798. Accessed Nov. 1, 2022.

[11] "2021 Employer Health Benefits Survey." Kaiser Family Foundation, Nov. 10, 2021. https://www.kff.org/report-section/ehbs-2021-section-9-prescription-drug-benefits/. Accessed Nov. 1, 2022.

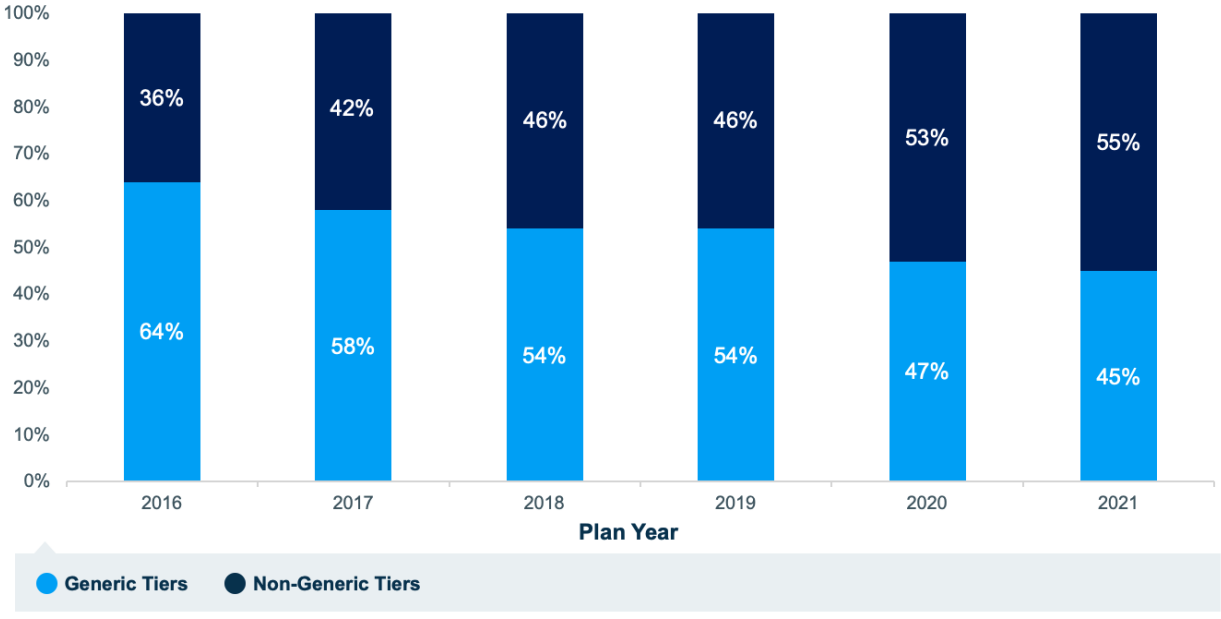
drug tiers (Figure 1).[12] Specialty drug tiers are known for having coinsurance type cost-sharing – a certain percentage of the cost of the drug. It can be as high as 30% in Medicare Part D.

Figure 1: Distribution of Generic Drugs on Part D Formulary Tiers, 2016-2021.



Source: Avalere Health. Accessed Oct. 28, 2022.

Figure 2: Distribution of Generic Drugs on Generic and Non-Generic Tiers, 2016–2021.



Source: Avalere Health. Accessed Oct. 28, 2022.

[12] Avalere. "Generic Drug Placement on Part D Generic Tiers Declines Again in 2021," March 11, 2021. Generic Drug Placement on Part D Generic Tiers Declines Again in 2021 | Avalere Health. Accessed Nov. 1, 2022.

Many generic formulations are covered by insurance formularies but may require copays, prior authorizations, or alternative step therapies before coverage. Copayments are the predominant form of cost-sharing for generic drugs. Generics not on the preferred tier may be subject to higher cost-sharing compared to preferred generic drugs. A separate Kaiser Family Foundation report identified most Medicare Part D enrollees (86%) pay less than $10 for generic drugs, but many pay up to $100 copay or up to 50% coinsurance depending on the generic drug and the formulary tier.[13] Oregon Medicaid has no copay for covered generics.

Generic drug shortages occur when demand exceeds supply and are usually a result of low profitability, loss of quality, company mergers, complex supply chains, natural disasters, and regulatory hurdles. Shortages disrupt patient care and can be considered an emerging public health crisis. The first tracking of national drug shortages began in 2001 and peaked in 2011.[14]

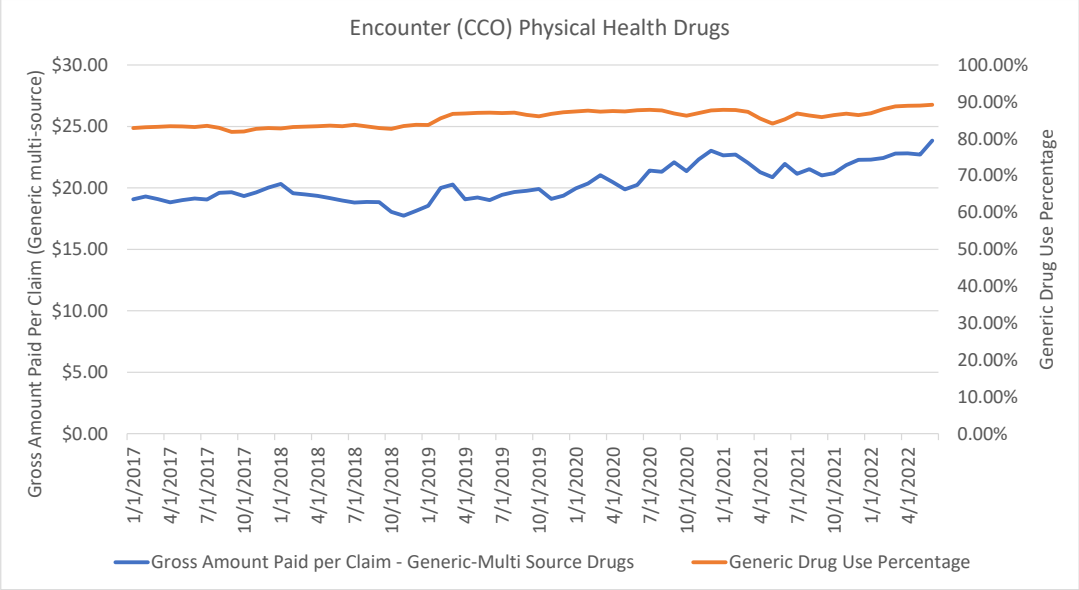
The products on the FDA national shortage list are typically low-cost generics used by hospitals. That is why Civica Rx was created by a consortium of hospital systems using their own capital and philanthropic funding to contract for some of these hospital products, which are distributed on a cost basis among the participating facilities.[15] Eventually, the organization intends to manufacture these products directly rather than contracting out the manufacturer.

It is impossible to assess the impact of generic drug prices on Medicaid spending since there are thousands of generic drugs and numerous manufacturers of each drug. However, the Association of Accessible Medicines has determined that utilization of generics relative to the branded counterpart saved Oregon Medicaid $674 million or $1,002 per enrollee in 2020.[16]

Figure 3 shows the gross amount that Oregon Medicaid providers paid on average per claim on generic-multi source physical health drugs (rebates not subtracted) from 2017 to quarter 1 of 2022. The figure also indicates the generic drug use percentage resulting in 80-90% of generic drugs being utilized between 2017-2022.

[13] Cubanski, Juliette, and Damico, Anthony. "Key Facts About Medicare Part D Enrollment, Premiums, and Cost Sharing in 2021." Kaiser Family Foundation, June 8, 2021. https://www.kff.org/medicare/issue-brief/key-facts-about-medicare-part-d-enrollment-premiums-and-cost-sharing-in-2021/. Accessed Nov. 1, 2022.
[14] Jacob, Elsen C., PharmD. "Factors Involved in U.S. Generic Drug Shortages." U.S. Pharmacist, June 18, 2020. https://www.uspharmacist.com/article/factors-involved-in-us-generic-drug-shortages.
[15] Civica Rx., 2022. https://civicarx.org/. Accessed Nov. 1, 2022
[16] "Our Interactive Savings Map." U.S. Generic and Biosimilar Medicines Savings Report 2021. Association for Accessible Medicines, October 2021. https://accessiblemeds.org/resources/blog/2021-savings-report#map. Accessed Nov. 1, 2022.

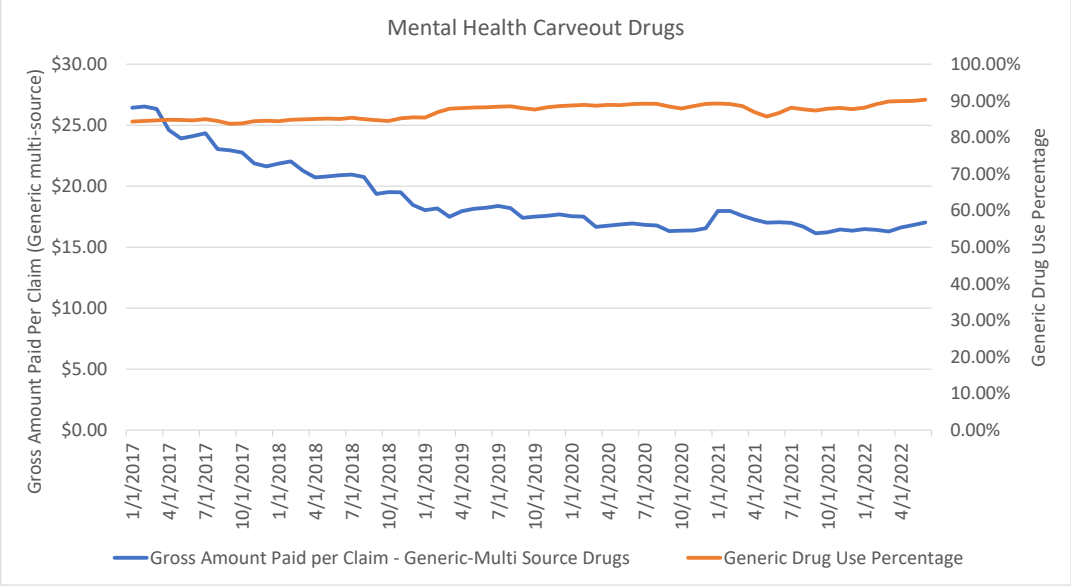
Figure 3: Medicaid encounter prices and percentage of physical health drugs.



Data provided by Oregon State University Drug Use Research and Management, https://pharmacy.oregonstate.edu/DRUG-POLICY. Accessed Oct. 28, 2022.

Mental health drugs also impact Medicaid generic drug pricing. Figure 4 illustrates that the gross amount paid per generic-multi source drugs has declined from 2017 through the first quarter of 2022. Although a steady decrease in pricing is indicated, the generic drug use percentage resulted in 80-90% of generic drugs being utilized between 2017-2022.

Figure 4: Medicaid encounter prices and percentage for mental health carveout drugs.



Data provided by Oregon State University Drug Use Research and Management, https://pharmacy.oregonstate.edu/DRUG-POLICY. Accessed Oct. 28, 2022.

Regulatory review can be time-consuming and the process can delay market entry of generic drugs. Federal legislative action could streamline the regulatory review process to speed approvals for safe and effective products.

The FDA's Drug Competition Action Plan is designed to improve the approval framework for generic drugs, making it more transparent, efficient, and predictable —to speed up the review process while maintaining rigorous scientific standards.[17] The FDA has found that generic drug applications are often incomplete or inaccurate, slowing down the approval of all applications. In 2022, the agency issued new guidance for the industry to improve the quality and accuracy of generic drug applications. The goal is to reduce the number of times an application has to be resubmitted for review because of manufacturer errors and omissions in the application. The agency also issued guidance on its actions if a manufacturer does not resubmit an application within the FDA timeframe.

Impact on generic drug market

PBMs manage prescription drug plans for insurance companies, Medicare part D plans, and large employer plans. They negotiate directly for drug price concessions which lower the net cost of a drug for insurance companies which can slow the growth in premiums and/or reduce patient costs at the point of service.

Practices impacting generic drug availability include pay for delay, patient assistance programs, and increased rebates for brand drugs for formulary placement to maintain the current number of patients (rather than switching patients to a new generic). Barriers to market entry may include brand drug manufacturers being protective in providing samples to generics manufacturers, companies using Risk Evaluation and Mitigation Strategy (REMS) programs to block or delay generic versions of drugs, and a patent system that allows brand manufacturers to extend market exclusivity.[18]

Manufacturers of high-cost brand drugs increasingly offer significant patient assistance programs that offset the sometimes-substantial patient cost-sharing imposed by insurance companies. The result is that doctors may prescribe the high-cost patented product rather than an alternative generic treatment because the patient cost is lower. Thus, the insurance and PBM companies lower their net cost of the branded drug to an amount lower than the cost of

[17] "FDA Drug Competition Action Plan: Helps remove barriers to generic drug development and market entry so that consumers can get access to needed medicines." U.S. Food & Drug Administration, Oct. 21, 2022. https://www.fda.gov/drugs/guidance-compliance-regulatory-information/fda-drug-competition-action-plan#game. Accessed Nov. 1, 2022.

[18] "Overpatented, Overpriced. Curbing patent abuse: Tackling the root of the drug pricing crisis." The Initiative for Medicines, Access, and Knowledge (I-MAK), September 2022. https://www.i-mak.org/wp-content/uploads/2022/09/Overpatented-Overpriced-2022-FINAL.pdf. Accessed Nov. 1, 2022.

the generic, and drug companies receive a higher volume of branded prescriptions written. In these scenarios, the generic drug has difficulty gaining market share at a lower price.

Another hidden cost that favors branded drugs over generics is the administrative burden on medical practices to prescribe high-cost drugs. With insurance programs being different and changing annually, there is a high administrative burden to understand the individual formularies, submit the prior authorization paperwork, and determine which drug has patient assistance programs, when needed. Only large medical systems can afford the full-time pharmacist and other support staff necessary to do this type of legwork, often at a financial loss. Small practices do not have the resources and will stick to tried and true branded medications to avoid this hidden unreimbursed effort.

Non-profit pharmaceutical companies like Civica Rx aim to provide competitive list prices of drugs and sell directly to large purchasers like the Veterans Administration and hospital systems.[19] They do not eliminate the rebate system favored by health insurance companies and PBMs, however, they have recently partnered with a non-profit PBM and may cause enough market disruption to reduce the excessive profits of PBMs and insurance companies.[20] Still, there is no requirement that the purchasers of Civica Rx drugs pass along savings to patients.

As discussed previously, biologics (or large molecule drugs) are made from living organisms, making their manufacturing more complex than small molecule drugs made from non-living chemical ingredients.[21] Biologics are typically injected or infused small molecule drugs, tablets, capsules, or oral products. The first biologic market entrant in a class is called the reference product. A subsequent highly similar biologic is called a biosimilar. The biologic/biosimilar relationship is conceptually the same as brand/generic, except that biosimilars are not always interchangeable in the way brands and generics are. Examples of biologic drugs are insulin, growth hormone, vaccine, and monoclonal antibodies. Biologic structures are more complex to manufacture relative to small molecule drugs, and there is more variability in the finished biologic product than in a pill or tablet.

---

[19] Dredge, Carter, MHA, and Scholtes, Stefan, PhD. "The Health Care Utility Model: A Novel Approach to Doing Business." The New England Journal of Medicine Catalyst, July 8, 2021. https://catalyst.nejm.org/doi/full/10.1056/CAT.21.0189 Accessed Nov. 1, 2022.

[20] "EmsanaRx Joins CivicaScript to Make Lower-Cost Generic Medicines Available to its Pharmacy Benefit Members." Civica Rx, June 14, 2022. https://civicarx.org/emsanarx-joins-civicascript-to-make-lower-cost-generic-medicines-available-to-its-pharmacy-benefit-members/. Accessed Nov. 1, 2022.

[21] Spain, Rebecca, MD, MSPH, Wallin, Mitchell, MD, MPH, Maloni, Heidi, PhD, Tortorice, and Kathy, PharmD. "Multiple Sclerosis Centers for Excellence: MSCoE Approach to Generic and Biosimilar Disease Modifying Therapies." U.S. Department of Veteran Affairs, March 18, 2021. https://www.va.gov/MS/Professionals/medications/Approach_to_Generic_and_Biosimilar_Disease_modifying_therapies.asp. Accessed Nov. 1, 2022.

Europe has moved much faster to approve biosimilar products to compete on price with reference biologics products. The European Medicines Agency (EMA), the European equivalent of the FDA, approved the first biosimilar in 2006. Since then, over 96 biosimilars have been approved for various indications, and Europe has seen no unexpected or unusual adverse reactions.

The 2009 Biologics Price Competition and Innovation Act established the regulatory framework for an abbreviated FDA approval process for biosimilars. Critical requirements for FDA approval of biosimilars are animal studies, including toxicity, a clinical (human) study to demonstrate safety, purity, and potency in one or more indications for which the reference product is licensed, and the expectation of the same clinical result as the reference product, and no increased risk or decreased efficacy caused by the switch of the reference to biosimilar product.[22] Notably, a biosimilar only requires evidence of clinical efficacy in one of the reference product's indications, with the other indications approved for the biosimilar by extrapolation.

Biosimilar competition aims to create product price competition among reference products and biosimilars. Similar to generic manufacture, a biosimilar sponsor can rely on the safety and efficacy work completed for the reference product, product development costs should be lower, approval times should be faster, and more products should be brought to market. There are 38 biosimilar products on the market as of September 2022.[23]

Generic Shortages

Generic drug shortages have become a more prominent issue in the supply chain and create access issues to often lifesaving medications or treatments. Shortages involve a number of complex economic factors based on both private and public sector decision making.

The FDA defines drug shortages as "a period when the demand or projected demand for the drug within the United States exceeds its supply."[24] They can worsen patient health outcomes based on the need to delay treatment or change treatment regiments, which in some cases can mean substituting less effective drugs.

---

[22] "Biosimilars." U.S. Food & Drug Administration, Sept. 16, 2022. https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/biosimilars. Accessed Nov. 1, 2022.

[23] Stewart, Judith, BPharm. "How many biosimilars have been approved in the United States?" Drugs.com, Sept. 29, 2022. https://www.drugs.com/medical-answers/many-biosimilars-approved-united-states-3463281/. Accessed Nov. 1, 2022.

[24] Hakur, Emily. "CDER Conversation: FDA's drug; shortages prevention strategies." U.S. Food & Drug Administration, Feb. 5, 2015. https://www.fda.gov/drugs/news-events-human-drugs/cder-conversation-fdas-drug-shortages-prevention-strategies. Accessed Nov. 9, 2022.

The FDA convened an inter-agency Drug Shortages Task Force in 2018. It issued a report identifying the three (3) root causes for addressing them.[25] Root causes included;

1. Lack of incentives for manufacturers to produce less profitable drugs;
2. The market does not recognize and reward manufacturers for mature quality management systems;
3. Logistical and regulatory challenges make it difficult for the market to recover after a disruption.

The Task Force noted in its conclusion: Given the potential scale of impacts from drug shortages, and the fact that these impacts have been continually underestimated, it is likely that drug shortages will continue to persist absent major changes in the marketplace.[26]

Researchers have estimated that hospitals and health systems spend between $216 million and $359 million in indirect costs and approximately $200 million in direct costs to address generic shortages. Indirect costs can include pharmacist and pharmacy technician time, and others who must procure alternative medications at inflated prices, ration available supply, evaluate alternative courses of treatment, update information technology systems, reschedule surgeries or procedures, and educate staff of changes based on availability.[27]

In recent years, there have been private market attempts to blunt the impact of generic drug shortages. Civica Rx, a non-profit drug manufacturer in California, has begun manufacturing short supply drugs for hospitals and health systems to bring stability, affordability, predictability, and transparency to the generic supply chain.[28] Civica Rx was created to address chronic drug shortages and the uncontrolled price increases of essential generics driven by shortages.[29] The Mark Cuban Cost Plus Pharmacy is also ramping up a production facility to manufacture drugs in short supply which will include the sterile filling and packaging of drugs and injectables to help meet short supply demands.[30]

As various sectors of the market have stepped up to address shortages, it remains to be seen whether others will follow, or if shortages will increase without federal government intervention. The only state to take action thus far is California where the CalRx initiative was

---

[25] "Drug Shortages: Root Causes and Potential Solutions." U.S. Food & Drug Administration, 2019. http://www.fda.gov/media/131130/download. Accessed Nov. 9, 2022.
[26] Jacob, Elsen C., PharmD. "Factors Involved in U.S. Generic Drug Shortages." U.S. Pharmacists, June 18, 2020. https://www.uspharmacist.com/article/factors-involved-in-us-generic-drug-shortages. Accessed Nov. 9, 2022.
[27] Ibid.
[28] "Civica Joins the End Drug Shortages Alliance." Civica Rx, June 30, 2022. https://civicarx.org/civica-joins-the-end-drug-shortages-alliance/#. Accessed Nov. 9, 2022.
[29] "Our Essential Medications." Civica. https://civicarx.org/our-medications/. Nov. 9, 2022.
[30] "Mark Cuban Cost Plus Drug Company Celebrates Construction Milestone for Dallas Headquarters." Cision PR Newswire, Feb. 2, 2022. https://www.prnewswire.com/news-releases/mark-cuban-cost-plus-drug-company-wwwcostplusdrugscom-celebrates-construction-milestone-for-dallas-headquarters-301473750.html

passed into law. The law requires the California Health and Human Services Agency (CHHSA) to enter into partnerships to produce or distribute generic prescription drugs that will address generic drug shortages, improve patient access, and generate savings for state purchasers, private payers, and consumers.[31]

[31] https://www.nashp.org/california-enacts-law-to-produce-generic-prescription-drugs/. Accessed Nov. 9, 2022.

Oregon Prescription Drug
Affordability Board

SB 844, Section 5 Report

A Report for the Oregon Legislature
December X, 2022

Oregon Prescription Drug
Affordability Board

Board Members

Akil Patterson, Chair
Shelley Bailey, Vice Chair
Dr. Richard Bruno
Dr. Amy Burns
Dr. Daniel Hartung
Robert Judge
John Murray
Dr. Rebecca Spain

For more information, please contact:

Ralph Magrish
Executive Director

Cortnee Whitlock
Program and Policy Analyst

Prescription Drug Affordability Board
350 Winter Street NE
Salem, OR 97309-0405
971-374-3724
pdab@dcbs.oregon.gov
dfr.oregon.gov/pdab

Table of Contents

Introduction

The Prescription Drug Affordability Board held its inaugural meeting on June 23, 2022, to carry out its mission of making prescription drugs more affordable for Oregonians. Appointed by the Governor and confirmed by the Oregon Senate, these board members include medical doctors, a university professor, pharmacists, and health advocates.

The board convened eight times in 2022, creating policies and administrative rules required for future rulemaking and public records requests. It has listened to consumer and stakeholder concerns, studied the complex distribution and payment system of prescription drugs and the generic drug market, and identified specific areas of future exploration to make prescription drugs more affordable in this state. The board received presentations from state and national experts on a range of topics, including upper payment limits, pharmacy benefit managers, and drug patent law. When the legislature created the board in 2021, it directed the board to prepare studies and recommendations for the legislature in 2022-2023.

The board is presenting the three reports described in its enabling legislation, Senate Bill 844:

- Distribution and payment system of prescription drugs and its impact on consumer prices
- Generic drug market's relationship to prescription drug costs
- Price trends and the board recommendations for making prescription drugs more affordable for Oregonians

Due to implementation delays, the board will conduct affordability reviews to identify nine drugs and one insulin product that it determines may create affordability challenges for Oregonians and report findings to the legislature in December of 2023.

In January 2023, the foundation of the board's work begins with the rulemaking process, including writing rules and holding public hearings to establish criteria, policies, and best practices to conduct affordability reviews. Once review criteria and rules are in place, the board will coordinate with the Prescription Drug Price Transparency program to compile and provide its first annual review of nine drugs and one insulin product.

The board has accomplished much in its six months of existence, including studying the drug distribution and payment system and the generic drug market. As a result of these 2022 studies, the board has compiled a list of recommendations for the legislature to consider to make prescription drugs more affordable in Oregon.

Overview

The Prescription Drug Affordability Board (PDAB) was established under Senate Bill 844 and supported by the Department of Consumer and Business Services (DCBS). The PDAB aims to

protect residents of the State of Oregon, state and local governments, commercial health plans, health care providers, pharmacies licensed in the state, and other stakeholders within the health care system of Oregon from the high costs of prescription drugs.

PDAB is a board with five members and three alternate members with expertise in healthcare economics and clinical medicine. The Senate appointed the board in June 2022, with additional members appointed in September 2022. The board will conduct affordability reviews to determine whether a drug presents affordability challenges to Oregon residents, health systems, and health inequities for communities of color in Oregon.

The board has rulemaking 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 the program and board administration costs.

Senate Bill 844, Section 5 reporting

The board is required by statute to report to the legislature and the Health Care Cost Growth Target program at the Oregon Health Authority on price trends of the prescription drugs that are included in reports submitted to the Drug Price Transparency program at DCBS and provided to the board for its affordability reviews.

Section 5(1): price trends

As the board will not begin criteria development and rule writing around affordability reviews until 2023 due to delays mentioned previously, the PDAB will not receive its first quarterly list of drugs for consideration until March of 2023. Despite these delays, the board will review the information found in the 2022 Drug Price Transparency Annual Report in preparation for its work ahead.[1]

Key findings of that report include:
Placeholder note: content embargo pending 2022 Drug Price Transparency Annual Report release on Dec. 1, 2022.

Section 5(2): affordability review

Rulemaking for affordability review criteria must be promulgated before reviews may begin. As the transparent rulemaking process will take 4 to 6 months, including requirements in HB 2993 (2021), the PDAB received an extension on the deliverable date for this requirement. PDAB expects to adopt administrative rules specifying criteria for affordability reviews no later than June 1, 2023.

[1] "Prescription Drug Price Transparency Results and Recommendations – 2022." Oregon Drug Price Transparency Program, Department of Consumer and Business Services, to be published Dec. 1, 2022. https://dfr.oregon.gov/drugtransparency/Pages/annual-reports.aspx. Accessed Nov. 7, 2022.

Given the depth and breadth of analysis and decision making involved, the board will take the remainder of 2023 to conduct the affordability reviews.

Section 5(3): recommendations

For our inaugural reporting requirements, the PDAB is submitting consolidated recommendations for the following provisions of Oregon Revised Statutes;

- ORS 646A.696(3): Recommendations, if any, for legislative changes necessary to make prescription drug products more affordable in this state
- OR Laws 2021, ch 598, § 7, *compiled as a note after* ORS 646A.689: Recommendations for policies to lower the list price of prescription drugs sold in this state and for legislative changes necessary to implement the policies[2].

The consolidated recommendations include those "primary" recommendations to meet obligations in ORS 646A.696(3) and a set of optional recommendations for future study. The PDAB has opted to couch these as optional future study contexts based on their complexities, anticipated controversies, and a lack of sufficient time to adequately prepare them as formal recommendations. These topics will warrant robust stakeholder engagement and the PDABs complete understanding of the issues prior to consideration for advancement.

[2] Oregon Laws 2021, chapter 646A, section 7. https://www.oregonlegislature.gov/bills_laws/ors/ors646A.html.

Oregon Prescription Drug Affordability Board

Proposed Recommendations for PDAB Reports

Primary Recommendations

Implement Upper Payment Limits (UPLs)

As a concept, an upper payment limit is a state-level analog to the pharmaceutical rate setting that exists in some form in most wealthy nations or the recently created price "negotiation" authority created for Medicare by the federal Inflation Reduction Act of 2022. Colorado has a PDAB with the authority to establish statewide upper payment limits on 12 drugs per year. Maryland's PDAB has authority to implement upper payment limits for state and local government purchasers. The Oregon legislature proposed UPLs in the original language in PDAB's governing statute Senate Bill 844, which allowed the Board to establish upper payment limits to all prescription drug sales and reimbursement claims in the state of Oregon. The UPL language was removed under Senate Amendments to Senate Bill 844. The Oregon Board can now only track and study these rate-setting efforts as well as additional efforts in other states that are working on prescription drug affordability. The PDAB recommendation is to grant it authority to set upper payment limits for state and local government purchasers. **[Section 7]**

Transparency in supply chain rebates

The price of a prescription drug is influenced by several factors, including the interactions and financial negotiations between pharmaceutical supply chain entities. Several of these entities can influence the cost of the drug to consumers, either at the pharmacy counter, through consumer health insurance premiums, or the impact of drug costs on health care system costs generally.

This recommendation would require Pharmacy Benefit Managers (PBMs) to report information to the Drug Price Transparency (DPT) program at DCBS. Specifically, the PDAB recommends that the DPT program be given statutory authority to collect the following information from PBMs annually:

- The aggregated dollar amount of rebates, fees, price protection payments, and any other payments the PBM received from manufacturers related to managing pharmacy benefits for health insurance carriers issuing health benefit plans in the state.
- The aggregated dollar amount of rebates, fees, price protection payments, and any other payments the PBM received from manufacturers that were:
    - Passed to carriers issuing health benefit plans in this state; or
    - Passed to enrollees at the point of sale of a prescription drug in this state; or
    - Retained as revenue by the pharmacy benefit manager.

The PDAB recommends that this information be aggregated and published by the DPT program annually to its website in a manner that does not disclose confidential information of any PBM.

This additional reporting will allow the PDAB and policymakers to more fully understand what influences and contributes to the cost of the drug to the consumer. **[Section 5 & 7]**

Drug Price Transparency (DPT) program to expand reporting requirements for patient assistance programs

Patient assistance programs have been a source of controversy in recent legislative sessions. Drug manufacturers argue that patient assistance helps patients whose insurance does not fully cover the cost of a needed medication. Insurance carriers argue that patient assistance undermines their efforts to control healthcare costs by incentivizing patients to use expensive brand-name drugs even when a generic alternative is available. Patient advocates have also argued for a ban on "co-pay accumulators" – that is, insurance plan design that does not credit third-party payments (such as patient assistance) against an individual's deductible or out-of-pocket maximum.

However, as currently structured, the DPT program's patient assistance program reporting is poorly matched to the market landscape. New drug reports do not require any patient assistance program reporting, and most price increase reports are for generic drugs, which are extremely unlikely to maintain a patient assistance program.

The PDAB recommends removing the patient assistance program reporting requirement from DPT price increase reports and requiring all manufacturers to report annually on all patient assistance programs they maintain or fund. Co-pay accumulators interact with patient assistance programs, and there have been proposals to the legislature to ban the use of co-pay accumulates to understand the interaction between co-pay accumulates and patient assistance programs. This will remove the reporting requirement in the DPT price increase reports while also allowing collection of more comprehensive data on patient assistance. The enhanced data will provide deeper and more informed analysis to help the DPT program, the Board, and the

legislature better understand the roles of both patient assistance and co-pay accumulators in developing future policy. **[Sections 5 & 7]**

Expand reporting to more insurers for the Drug Price Transparency program
Health insurance carriers are required to submit rate filings only if they offer individual or small group health benefit plans. Under the Prescription Drug Price Transparency Act (HB 4005), these health plans are required to report spending on prescription drugs at the time of the rate filing. Some commercially insured employer plans (that are not self-funded) do not participate in these markets and are not required to submit these drug spending reports. This may result in an incomplete picture of health plan spending on drugs in Oregon. The policy proposal is to separate the rate filing and the drug spend reporting and expand the application of the required drug spend reporting to all state regulated health insurance carriers in Oregon. **[Section 5 & 7]**

Require patient advocacy organizations to publicly disclose funding sources
Many patient organizations receive funding from pharmaceutical manufacturers with products related to the interests of the patient organization. Often, patient groups will oppose state-level pharmaceutical cost containment policies, and their policy position may be influenced by financial support. What is only sometimes clear to policymakers is that these groups may be closely aligned with the industry. It can be helpful to policymakers to understand financial relationships that may influence patient group advocacy. Nevada has a law that requires patient groups to disclose their industry funding sources publicly, which could be modeled:

(a) Compile a report which includes:
  (1) For each such contribution, the amount of the contribution and the manufacturer, third party or pharmacy benefit manager or group that provided the payment, donation, subsidy or other contribution; and
  (2) The percentage of the total gross income of the organization during the immediately preceding calendar year attributable to payments, donations, subsidies or other contributions from each manufacturer, third party, pharmacy benefit manager or group

[Section 7]

<u>Optional Future Study Topics</u>

Fee Assessments for unsupported price increases
The Institute for Clinical and Economic Review (ICER) produces an annual report/analysis of ten prescription drugs that significantly impact US healthcare spending and have significant price increases for which there was no supporting evidence of the need for the price increase. The intent of this policy is that states could penalize manufacturers with unsupported price increases. Legislation has been introduced, which would tax the ICER-list manufacturers on the

increment of revenue in the state generated by the price increase. Bills on this policy have been introduced in four states (Oklahoma, Rhode Island, Hawaii, and Maine), but none have been enacted.

Taxing drug price increases that are greater than the rate of inflation
This is similar in concept to the initial policy proposal, except that the scope of application is much greater. Depending on the inflation rate in a year, hundreds of drugs could have price increases above the inflation rate. Administratively this could be difficult for a state to manage and ensure compliance. A new federal law will apply this policy to Medicare Part B and Part D drugs. Alternatively, the state policy could impose a penalty on price increases of x percent above the inflation rate, which would capture more egregious pricing behavior and reduce the administrative burden on state administration.

Expand the Medicare negotiated price (called Maximum Fair Price) statewide
This proposal would expand the MFP as an upper payment limit for all prescription drug transactions in Oregon, not just Medicare.

Drug rebate application to cost sharing
This proposal would pass through the manufacturer's drug rebate to the consumer at the point of service. This would be operationalized by limiting the past through amount of some portion of the rebate, assuming the rebate is greater than the consumer cost share at the point of service.

While drug manufacturers promote and support limiting the pass-through amount, they also want the amount of a rebate on a drug to remain a trade secret. This means the burden of implementing the policy is on the insurer. In contrast, the policy could be implemented by manufacturers similar to the operational mechanics of manufacturer copay assistance cards.

Limit prescription drug formulary changes
Medicare limits changes to a Part D drug plan during the plan year. A drug cannot be removed from a formulary mid-year except for FDA initiated recalls or other federal safety concerns. A drug cannot be moved to a higher cost tier during the plan year except if its generic equivalent has come to market.

Voting Options

1. Full recommendation to include
2. Do not recommend
3. Recommend PDAB study further for future (recommendations)

PDAB Rulemaking Steps

1. **Model Rules for Rulemaking and Public Records Request** | June 23, 2022
   Board approval

2. **Temporary Model Rules** | June 27, 2022
   Filed with the Secretary of State

3. **Rules Advisory Committee** | Aug. 25, 2022
   Stakeholder meeting with drug manufacturers, insurers, PBMs, others

4. **Permanent Model Rules** | Sept. 28, 2023
   Filed with the Secretary of State

5. **Rules Hearing** | Oct. 25, 2022
   Stakeholder meeting with drug manufacturers, insurers, PBMs, others

6. **Final Model Rules** | Nov. 16, 2022
   Board final approval

OFFICE OF THE SECRETARY OF STATE
SHEMIA FAGAN
SECRETARY OF STATE

CHERYL MYERS
DEPUTY SECRETARY OF STATE

ARCHIVES DIVISION
STEPHANIE CLARK
DIRECTOR

800 SUMMER STREET NE
SALEM, OR 97310
503-373-0701

NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 925
DEPARTMENT OF CONSUMER AND BUSINESS SERVICES
PRESCRIPTION DRUG AFFORDABILITY BOARD

FILED
09/28/2022 3:37 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Model Rules for Rulemaking and Public Records Requests

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 11/01/2022 5:00 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

CONTACT: Karen Winkel
503-947-7694
karen.j.winkel@dcbs.oregon.gov

350 Winter St. NE
Salem,OR 97301

Filed By:
Karen Winkel
Rules Coordinator

HEARING(S)

Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 10/25/2022
TIME: 1:00 PM
OFFICER: Cassie Soucy and Cortnee Whitlock
ADDRESS: Labor & Industries Building
350 Winter St. NE
Basement, Conf Rm E
Salem, OR 97301
SPECIAL INSTRUCTIONS:
This is a hybrid meeting conducted in-person and virtually via Microsoft Teams:

Join on your computer, mobile app or room device
Meeting ID: 279 814 617 663
Passcode: DYmV6M

Or call in (audio only)
+1 503-446-4951,,187471096# United States, Portland
Phone Conference ID: 187 471 096#

NEED FOR THE RULE(S)

The Prescription Drug Affordability Board (PDAB) was enacted as part of Senate Bill 844 (2021) within the Department of Consumer and Business Services (DCBS) with the purpose to protect consumers and other entities from the high cost of prescription drugs. The law provides authority for the PDAB to adopt rules necessary for the administration of the board (ORS 646A.693(18)).

The Administrative Procedures Act requires state agencies and boards to adopt rules related to the procedure. The

Attorney General's Office has provided model rules for agencies and boards to utilize for creating the process to engage in these crucial functions (ORS 183.341). The Attorney General's Office recommends that all agencies and boards adopt the model rules for procedure around rulemaking to comply with the Administrative Procedures Act.

On June 23, 2022, the first rulemaking action that the PDAB conducted was to approve temporary rules that adopt the model rules for rulemaking and public records requests:

OAR 925-100-0001 provides a legal framework for the PDAB to engage in rulemaking as authorized by SB 844 (2021), consistent with authorities granted under ORS 183.341.
OAR 925-100-0002 defines requirements for notification of rulemaking by the PDAB.
OAR 925-100-0003 adopts Oregon's Public Records Law (ORS 192) requirements into PDAB rules.

A rules advisory committee met on August 25, 2022, and consisted of stakeholders from drug manufacturers, insurers, and PBMs.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

Draft rules are available from Karen Winkel, Rules Coordinator, Division of Financial Regulation located at 350 Winter St. NE, Salem, OR 97301 and are available on the division's website:

https://dfr.oregon.gov/laws-rules/pages/proposed-rules.aspx

STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE

Based on currently available information, the rules will not directly affect racial equity in this state because the rules are for standard rulemaking and public record processes. The PDAB is tasked with evaluating the cost of prescription drugs including ones that contribute to health inequities for communities of color. These model rules allow the PDAB to function within its statutory authority and evaluate the impacts of prescription drug costs on communities of color.

FISCAL AND ECONOMIC IMPACT:

ORS 646A.693 has a significant economic impact on prescription drug manufacturers. The permanent rules proposed however are related to the administrative processes for rulemaking, rulemaking notices, and public records. These rules are unlikely to have an impact on prescription drug manufacturers or on any small businesses based on information available to the board.

COST OF COMPLIANCE:

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

(1) Based on currently available information, the proposed rules would not have a fiscal or economic impact on state agencies, local government units, or the general public beyond the statutory requirements. The proposed rules do not add any new requirements on public entities, but instead clarify the board's administrative processes pertaining to rulemaking, rulemaking notice, and public records.

(2)(a) Based on the information available to the board, it is unlikely that the proposed rules will impose compliance costs on small businesses. Pharmaceutical manufacturers are the primary business directly subject to the underlying statute. The board does not have data on the specific number of employees employed by pharmaceutical manufacturers.

Regardless, the rule amendments proposed relate to administrative processes for the board and do not have an impact on manufacturers beyond the underlying statutory requirements.

DCBS convened a Rulemaking Advisory Committee (RAC), which included representatives of prescription drug manufacturers, health insurers, pharmacy benefit managers, pharmacies, and consumer and patient advocates. Committee feedback suggested that it is unlikely that any of the manufacturers or other businesses are small businesses.

(2)(b) Based on the available information, including feedback from the RAC, the proposed rules do not impose additional compliance costs.

(2)(c) Based on current information, including feedback from the RAC, the proposed rules do not impose additional costs for professional services, equipment supplies, labor, and increased administration beyond the underlying statutory requirements.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

The rulemaking advisory committee was comprised of stakeholders within the pharmaceutical supply. This included representation of pharmacies and some pharmacies are small businesses.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

RULES PROPOSED:
925-100-0001, 925-100-0002, 925-100-0003

ADOPT: 925-100-0001

RULE SUMMARY: Provides a legal framework for the Prescription Drug Affordability Board (PDAB) to engage in rulemaking as authorized by SB 844 (2021), consistent with authorities granted under ORS 183.341.

CHANGES TO RULE:

925-100-0001
Model Rules for Rulemaking
The Model Rules for Rulemaking, OAR 137-001-0005 through 137-001-0100, in effect on Jan. 1, 2008, adopted by the Oregon Department of Justice under ORS 183.341, are adopted as the rules of procedure for rulemaking actions of the Prescription Drug Affordability Board. The full text of the Model Rules is available from the Department of Justice, the Prescription Drug Affordability Board, or on the Oregon State Archives website at: https://secure.sos.state.or.us/oard/viewSingleRule.action?ruleVrsnRsn=291164
Statutory/Other Authority: ORS 646A.693 - 646A.697
Statutes/Other Implemented: ORS 183.325 - 183.410

ADOPT: 925-100-0002

RULE SUMMARY: Defines requirements for notification of rulemaking by the PDAB.

CHANGES TO RULE:

925-100-0002
Notice of Rulemaking
(1) Except when adopting a temporary rule, the Prescription Drug Affordability Board will give prior public notice of the proposed adoption, amendment, or repeal of any rule by:¶
(a) Publishing notice of the proposed rulemaking action in the Secretary of State's Oregon Bulletin at least 21 days before the effective date of the rule;¶
(b) Notifying interested people and organizations on the Prescription Drug Affordability Board's notification lists of proposed rulemaking actions under ORS 183.335; and¶
(c) Providing notice to legislators as required by ORS 183.335(15).¶
(2) A person or organization may elect to receive email or hard-copy notification of proposed rulemaking actions of the Prescription Drug Affordability Board.¶
(a) A person or organization may elect to subscribe to the Prescription Drug Affordability Board's email notification service at:
https://public.govdelivery.com/accounts/ORDCBS/subscriber/new?topic_id=ORDCBS_732.¶
(b) A person or organization may elect to receive hard-copy notification by sending a request in writing, including the person or organization's full name and mailing address, to the following address:¶
Rules Coordinator¶
Prescription Drug Affordability Board¶
350 Winter St. NE¶
P.O. Box 14480¶
Salem, OR 97309-0405
Statutory/Other Authority: ORS 646A.693 - 646A.697
Statutes/Other Implemented: ORS 84.022, 183.335

ADOPT: 925-100-0003

RULE SUMMARY: Adopts requirements found in Oregon's Public Records Law (ORS 192) into PDAB rules.

CHANGES TO RULE:

925-100-0003
Public Records Requests
(1) Oregon's Public Records Law (ORS 192) provides that every person has a right to inspect any public records of a public body, except records that are exempt from disclosure.¶
(2) A public record request may be submitted in person, by U.S. Mail, fax or by email to the Prescription Drug Affordability Board (Board). The written request must include:¶
(a) The name and address of the person requesting the public record;¶
(b) The telephone number or other contact information of the person requesting the public record;¶
(c) A sufficiently detailed description of the record(s) requested to allow the Board to search for and identify responsive records; and the¶
(d) Date and signature of the person requesting the public record.¶
(3) Public records, except those exempt from disclosure, will be made available upon request for review and copies will be provided at a fee reasonably calculated.¶
(4) The Oregon Public Records Law allows agencies to recover their actual costs in fulfilling a public records request including actual costs for supplies, research, compilation, postage, shipping and staff time.¶
(5) Fees will be payable prior to fulfilling a public records request. If the fee is estimated to be greater than $25:¶
(a) The Board staff will provide the requestor with a written notice of the estimated amount of the fee.¶
(b) The public records request will not be fulfilled until the requestor confirms in writing that the requestor wants to proceed with the request.¶
(6) Standard fees for Public Records:¶
(a) Per page fees reflect current Oregon Department of Administrative Services policy;¶
(b) $5 for each true notarized certification;¶
(c) Other applicable fees: actual costs or best estimate of costs; and¶
(d) Miscellaneous fees may include archive retrieval costs, costs of software companies/contracts; other third party costs.¶
(e) No charge for the first 30 minutes of staff time for processing request. The hourly rate charged for additional staff time is based on the level of skill or expertise required to complete the work performed not the employee-level of the individual actually fulfilling the request.¶
(f) Clerical labor charges are $25 per hour; Managerial labor charges are $40 per hour; Professional (IT, HR, high-level Analyst) $75 per hour; and DOJ, special attorney and other applicable legal fees: at the actual hourly rate charged for Public Records Request-related services. Fees are subject to statutory limitation described in ORS 192.324.¶
(7) The Board may furnish copies of public information without charge or at a reduced fee if it is determined that the waiver or reduction of fees is in the public interest because providing access primarily benefits the general public under ORS 192.324.¶
(8) A person desiring a waiver or reduction in fees must submit a written request for a waiver.¶
(9) The Board Executive Director will consider each request on a case-by-case basis based on the information provided by the requestor and the totality of the circumstance at the time of the request.¶
(10) The Board Executive Director will make fee waiver or reduction decisions based on the guidelines outlined in the Oregon Department of Administrative Services Statewide Standardized Fee Process.
Statutory/Other Authority: ORS 646A.693 - 646A.697
Statutes/Other Implemented: ORS 192.324