Oregon Prescription Drug Affordability Board

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Agenda

Date: **December 14, 2022** | *Time*: **9:30 - 11:30 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
☐	Board approval of final reports: Rx Generic Drugs Report Rx Distribution and Payment System Report Price Trends for List of Rx	Cortnee Whitlock	45 minutes
☐	Board discussion, vote on 2023 meeting presentations	Ralph Magrish	15 minutes
☐	2023 work plan and rule development discussion: Affordability review criteria Fee development	Cortnee Whitlock	20 minutes
☐	Announcements	Ralph Magrish	5 minutes
☐	Public comment	Chair Patterson	10 minutes
☐	Adjournment	Chair Patterson	2 minutes

Next Meeting

January 18, 2023, 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, November 16, 2022
Draft Minutes

Call to Order and Roll Call
Chair Akil Patterson called the meeting to order at 9:33 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). John Murray (alternate).

Approval of the Minutes
Chair Akil Patterson asked if board members had any changes to the October 19, 2022, minutes on Pages 3-7 in the agenda packet: https://dfr.oregon.gov/pdab/Documents/20221116-PDAB-document-package.pdf. **Dr. Richard Bruno** moved to approve and **Vice Chair Shelley Bailey** provided a second.

MOTION by Shelley Bailey to approve the October 19, 2022, minutes.
Board Voice Vote:
Yea: Richard Bruno, Amy Burns, Daniel Hartung, Vice Chair Shelley Bailey, Chair Akil Patterson.
Nay: None.
Motion passed.

Program Update: Executive Director Ralph Magrish said staff would produce a quarterly newsletter beginning in December. He said the Drug Price Transparency program will hold a public hearing on Dec. 1, with details on Page 7 in the agenda packet: https://dfr.oregon.gov/pdab/Documents/20221116-PDAB-document-package.pdf. He will give a presentation during Legislative Days on Dec. 8 about the Prescription Drug Affordability Board and Drug Price Transparency program. He invited board members to provide a list of their requests for presentations in 2023 s at the December meeting. Ideas may include the Oregon State Pharmacy Association speaking on its recent report "Understanding Reimbursement Trends in Oregon: The High Cost of Low Prices," or the Oregon Primary Care Association speaking about 340B purchasing.

Patent Law: Ralph Magrish introduced **Tahir Amin**, founder and executive director of the Initiative for Medicines, Access & Knowledge (I-MAK), a nonprofit organization addressing structural inequities in how medicines are developed and distributed. Tahir Amin said when a drug company is developing a product, it takes out a patent in the research stages before a drug is approved for marketing. If something from the discovery is successful, the drug gets approved by the FDA. This step takes up the first eight years of the patent life. Once the drug gets to market, the company has 10-12 years of exclusivity, a limited monopoly in the marketplace when no one else can sell without consent. Most people think of 20-year patent terms, and once the patent ends, generic drugs, or biosimilar competition, will enter the market. His organization and other academics have found, however, that is not what is happening. He wants to shed light on how pharmaceutical companies are using the patent system to prolong that limited monopoly, holding on to exclusivity for longer, charge higher prices, and keeping competition at bay, all which leads to higher drug pricing. He discussed information from Pages 8-23 of the agenda document posted here: https://dfr.oregon.gov/pdab/Documents/20221116-PDAB-document-package.pdf. He recommends contacting congressional members and coordinating with other states to raise awareness about what drug companies are doing through the patent system.

Questions from the Board: Dr. Daniel Hartung asked about using marching rights to invalidate patents for publicly-funded drugs and other therapies. **Tahir Amin** said marching rights are when the government overrides patents of drugs that have received public fund, inviting competition. It is a struggle to get marching rights because it has never been used. In public-private partnerships, the signed contracts do not allow the government to use marching rights.

Dr. Rebecca Spain asked if Europe is a benchmark to compare with U.S. patents and if Europeans are happy with their patent system. **Tahir Amin** said he does not think Europe has the best patent system either. U.S. and Europe have the two biggest patent offices in the world. In Europe, companies cannot file applications repeatedly like they can in the U.S., accumulating patents used in litigation that suffocates people into settlements. Even in Europe, there is work to do because Europeans are paying high prices for drugs as well.

Chair Akil Patterson asked if patent games are an issue for the courts or the legislature. **Tahir Amin** said that, ultimately, it is with Congress. The courts became pro patent in the 1980s, a response to the tough economic times of the 1970s. Today, the courts are so patent friendly, it is very hard to get a patent challenge. The USPTO can make new rules, but ultimately, raising the bar to get a patent happens in Congress. A flurry of lobbying activity will follow to preserve the system, he predicts, but he is hopeful for the future.

Dr. Amy Burns asked if definitions around biosimilars have driven some of these challenges. **Tahir Amin** said there is a difference in how U.S. defines interchangeable versus non-interchangeable biosimilars. Many states look for a biosimilar that is interchangeable. A biosimilar company has to do extra effort in clinical trials in order to get that "interchangeable" status, as not every biosimilar approved by the FDA is interchangeable. In Europe, they do not have that same interchangeable criteria. It is not to say Europe is not doing enough trials, but there seems to be an extra level in the United States hindering competition to substitute a biosimilar for a biologic. In the generic space, showing bio-equivalency is more straightforward. Because it is so easy to file so many patents on a biologic drug given the nature of the product, it is rife with delays in getting these products to the market, he said. Many biosimilar companies do not want to participate in this process because it is too costly to get through patents and bureaucratic levels.

Board discussion of draft reports: **Cortnee Whitlock**, policy analyst, discussed the draft reports and sought board member feedback. The reports are located on Pages 24 – 74 in the agenda document: https://dfr.oregon.gov/pdab/Documents/20221116-PDAB-document-package.pdf. Here is the board's feedback:

Generics and DIRs

Dr. Rebecca Spain recommended distinguishing between generics and biologicals. **Dr. Amy Burns** suggested including physician-administered medications because of the difference in cost and distribution through the system**. Vice Chair Shelley Bailey, John Murray, Robert Judge, and Dr. Dan Hartung** recommended including a section about the impact on pharmacies of direct and indirect remuneration fees (DIR). **Robert Judge** said DIRs seem to be a revenue source for PBMs. **John Murray** said pharmacists try to do everything right to hit DIRs fees, whether it is drug evaluation or patient consultation, or generic implementation. The bar always moves, is always raised, and they never seem to hit it. He said it is more of a PBM profit motive than trying to improve actions at a pharmacy leveled. **Dr. Dan Hartung** recommended including rebates, which are also part of DIRs.

Fee for service and CCOs

Vice Chair Shelley Bailey recommended highlighting what percent of Medicaid claims in Oregon are fee for service (FFS) versus CCOs. Dr. **Daniel Hartung** recommends clarifying about the mental health carve out, which is included in the FFS section. Another important part of the Medicaid supply chain is the Federal Medicaid rebate.

The inflationary rebate, which is the new model for the Medicaid legislation, is an impotent discussion point because it differentiates Medicaid from the other sectors of the pharmacy market. **Robert Judge** said it would be beneficial to have discussions on Medicaid FFS and Medicaid CCO. Although CCOs are funded through state funds, it is mostly administered in the pharmacy arena through commercial PBMs that support the CCOs.

Ralph Magrish asked the chair about extending the meeting to accommodate the remaining agenda items. **Chair Akil Patterson** asked for a motion. **Vice Chair Shelley Bailey** moved to extend the meeting time and **Dr. Daniel Hartung** provided the second. **Dr. Amy Burns** said she cannot stay for the extended meeting time.
MOTION by Shelley Bailey to extend the meeting time.
Board Voice Vote:
Yea: Richard Bruno, Amy Burns, Daniel Hartung, Shelley Bailey.
Nay: None
Abstain: Akil Patterson
Motion passed.

Independent Pharmacy, Commercial Insurance
Vice Chair Shelley Bailey recommended changing the term "independent pharmacy" to "small chain and independent pharmacy." She said, when it comes to access and equity, small chain pharmacies closures are just as impactful to communities as an independent pharmacy because they are often the only pharmacy provider in certain geographic areas. **Dr. Amy Burns** suggested changing the heading employer-sponsored health insurance to commercial so it also includes individual or small group market. **Chair Akil Patterson** agreed about defining terms. **Robert Judge** said the report describes three markets – Medicaid, Medicare and commercial markets. **Vice Chair Shelley Bailey** agreed, but added a fourth area, separating out fee for service Medicaid versus managed Medicaid. **Chair Akil Patterson** suggested having a key with definitions and terminologies.

Prior Authorizations (PA)
Robert Judge recommended giving equal time to the reason PAs exist, making sure that right therapies get to right individuals at the right time at the right cost. **Dr. Amy Burns** agreed. Dr. **Rebecca Spain** said she was writing this portion from her prescribing perspective. She knows it is important to have cost containing measures. Prior authorizations sometimes do not make sense, she said. A solution would be to have subject experts on the diseases be part of creating prior authorization chains or tier chains. She gave an example of trying to prescribe a certain drug to a patient who now needed a less aggressive drug with lower risk ratio, but did not tolerate the one on the insurance formulary. She said it was very difficult to find a medication with a lower risk that would be paid for by the patient's insurance. The easiest thing to do would be to continue a higher risk drug because it was on their system. Physicians get into these nonsensical situations even though the system is set up with good intentions. **John Murray** said, as a pharmacist, he deals with the other half of it, when a patient comes in the pharmacy, the pharmacist explains the PA to the frustrated patient. Hopefully, the PA process is being improved or streamlined with technology. He understands the need and importance of step therapy to minimize cost and that use of generics is important. But he also understands the frustration. **Robert Judge** recommended the report give equal time to patient assistance programs and copay coupons.

Impact on underserved and disadvantaged populations
Robert Judge and John Murray suggested this section include the criticality of community pharmacies, small chain pharmacies in areas of the state that are underserved, especially in Eastern Oregon, where there are growing "pharmacy deserts" without adequate services. **Dr. Richard Bruno** recommended changing the title to

under-resourced to be more consistent. **Chair Akil Patterson** recommended being specific when it comes to issues impacting race, ethnicity, and age. Pharmacy deserts may also impact aging populations in rural communities and tribal communities who depend on rural pharmacies, including people on unrecognized tribal lands. He said it is important to recognize these aspects of the rural community discussion.

Generic Drug Report
Vice Chair Shelley Bailey and Dr. Amy Burns suggested adding PBM fees and administrative costs to the payor net cost portion on Page 7. **Vice Chair Shelley Bailey, John Murray, and Dr. Amy Burns** recommended adding a sentence about maximum allowable cost (MAC) and the lack of transparency, which is challenging for pharmacies.

Recommendations: Chair Akil Patterson said members would discuss recommendations before taking a vote on each. He said if board members have a potential conflict of interest, the chair will appoint an alternate to vote instead. Here are highlights of the discussion:

Recommendation 1: **Robert Judge** said he was uncomfortable with setting an upper limit payment because it is unexplored territory that needs further study. He is concerned about what it might do to pharmacies who get reimbursed for the drugs. **Dr. Richard Bruno** said he feels comfortable with upper payment limits based on the speakers who presented to the board last month. **Vice Chair Shelley Bailey** said she is also concerned about potential impacts. **Chair Akil Patterson** believes the board should have the authority to set upper payment limits, but it is a legislative decision. He thinks the board should send back the legislature's original language about upper payment limits, which was removed from the current SB 844. **John Murray** said if granted authority, the board does not have to use it if the board determines it is harmful to the overall supply chain. He does not want to damage an already fragile system, especially for urban or rural disadvantaged populations. **Dr. Rebecca Spain** said the board should give the best recommendations to the legislature. It does not mean it will be implemented. She trusts this board to make good recommendations. **Chair Akil Patterson** asked for a motion. **Dr. Richard Bruno** moved to approve the upper payment limit section as written and **Dr. Amy Burns** provided the second.
MOTION by Richard Bruno to approve Recommendation 1 Upper Payment Limits.
Board Vote:
Yea: Richard Bruno, Amy Burns, Daniel Hartung, Akil Patterson.
Nay: Shelley Bailey.
Motion passed.

Recommendation 2: **Robert Judge** proposed adding the phrase GPO, which are group purchasing organizations used or owned by PBMs, because GPOs create another layer of opacity in the rebate supply chain. **Vice Chair Shelley Bailey** made a motion to approve Recommendation 2 with the added language. **Dr. Amy Burns** provided the second.
MOTION by Shelley Bailey to approve Recommendation 2 transparency in supply chain rebates with the amendment of GPOs.
Board Vote:
Yea: Richard Bruno, Amy Burns, Daniel Hartung, Shelley Bailey, Akil Patterson.
Nay: None
Motion passed.

Recommendation 3: **Dr. Amy Burns** left the meeting and **Chair Akil Patterson** appointed **Robert Judge** as the alternate member to vote. **Vice Chair Shelley Bailey** moved to approve Recommendation 3 as is and **Robert Judge** provided the second.

MOTION by Shelley Bailey to approve Recommendation 3 DPT expand reporting requirements for patient assistance programs.
Board Vote:
Yea: Richard Bruno, Amy Burns, Daniel Hartung, Shelley Bailey, Akil Patterson.
Nay: None
Motion passed.

Recommendation 4: **Robert Judge** said he would abstain from voting due to a potential conflict of interest. The chair appointed alternate **Dr. Rebecca Spain** to vote. **Vice Chair Shelley Bailey** moved to approve Recommendation 4 as is and **Dr. Daniel Hartung** provided the second.
MOTION by Shelley Bailey to approve Recommendation 4 DPT expand reporting to more insurers.
Board Vote:
Yea: Richard Bruno, Daniel Hartung, Rebecca Spain, Shelley Bailey, Akil Patterson.
Nay: None
Motion passed.

Recommendation 5: **Robert Judge** said he would return to voting. **Vice Chair Shelley Bailey** moved to approve Recommendation 5 as proposed and **Dr. Daniel Hartung** provided the second.
MOTION by Shelley Bailey to approve Recommendation 5 require patient advocacy groups to disclose funding sources.
Board Vote:
Yea: Richard Bruno, Daniel Hartung, Robert Judge, Shelley Bailey.
Nay: None
Abstain: Akil Patterson
Motion passed.

Final Rule Making Approval: Cortnee Whitlock, policy analyst, reviewed the model rule process shown on Page 75 of the agenda packet: https://dfr.oregon.gov/pdab/Documents/20221116-PDAB-document-package.pdf.
Vice Chair Shelley Bailey moved to approve the final model rules and **Robert Judge** provided the second.

MOTION by Shelley Bailey to approve the final model rules.
Board Vote:
Yea: Richard Bruno, Daniel Hartung, Robert Judge, Shelley Bailey, Akil Patterson.
Nay: None.
Motion passed.

Public Comment: The chair allocated three minutes for public comment. He called on the people who signed up in advance to speak, Tonia Sorrell-Neal, Pharmaceutical Care Management Association, and Dharia McGrew, PhRMA. Both provided testimony to the board.

Adjournment: The meeting was adjourned at 12:10 p.m. **Vice Chair Shelley Bailey** made the motion, and **Robert Judge** provided the second.

MOTION by Shelley Bailey to adjourn the meeting.
Board Voice Vote
Yea: Richard Bruno, Daniel Hartung, Robert Judge, Vice Chair Shelley Bailey, Chair Akil Patterson.
Nay: None.
Motion passed.

DRAFT

2022 Report for the Oregon Legislature

Prescription Drug Distribution System and Generic Drug Reports Pursuant to Senate Bill 844 (2021)

December 6, 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:

Ralph Magrish, executive director

Cortnee Whitlock, program and policy analyst

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Acknowledgement

These reports were prepared by the following Perception Drug Affordability Board staff:

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Executive summary

Background

The Oregon Legislature created the Prescription Drug Affordability Board (PDAB) under Senate Bill 844 (2021) to evaluate the cost of prescription drugs and determine whether they present an affordability challenge to consumers and health systems in Oregon. The legislation also directed the board to study the prescription drug distribution and payment system and the generic drug market in Oregon and to bring recommendations about affordability back to the Legislature.

Process and activities

PDAB met for the first time on June 23, 2022, and convened eight times in 2022, creating policies and administrative rules required for future rulemaking. The board listened to consumer and stakeholder concerns, studied existing systems and the market, and identified specific areas of future exploration to make prescription drugs more affordable in Oregon. The board received presentations from state and national experts on various topics, including upper payment limits (UPL), pharmacy benefit managers (PBM), and drug patent law.

Reports and findings

In the board's inaugural set of reports and recommendations, PDAB considers the complexity of how drugs move through the supply chain and reimbursement mechanisms to consumers and how that process affects the cost of prescription medications.

Distribution and Payment System Report: The report highlights key elements of the prescription drug supply chain and implications for the delivery of cost-effective prescription drugs for Medicare, Medicaid, and commercial health insurance, and effects on patients and prescribers, especially in under-resourced communities. The report reviews policies implemented in other states and countries, the effectiveness of reverse auction marketplaces, and, in Oregon, consolidated drug purchasing and payor negotiations.

Generic Drug Report: The report considers how patents, shortages, contracts, and biosimilars affect the availability and cost of generic drugs. As generic drugs play a crucial role in providing

patients with safe, effective therapies at a low cost, the report reviews the degree to which generic drug prices affect insurance premiums, health insurance cost sharing, and annual spending for the Oregon Health Plan.

Recommendations

Price Trends and Recommendations Report: Consistent with SB 844, PDAB provides five primary recommendations for making prescription drugs more affordable for Oregonians.

Implement URLs:

The Oregon Legislature proposed UPLs in the original language of PDAB's governing statute, SB 844, which allowed the board to establish upper limits to all prescription drug sales and reimbursement claims in Oregon. The language was removed under Senate amendments. 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. PDAB's recommendation is to grant it authority to set a UPL for state and local government purchasers.

Transparency in supply chain rebates:

Require PBMs and group purchasing organizations (GPOs), which are either used or owned by PBMs to operate rebate programs, to report aggregated rebates and other payments from manufacturers annually to the Drug Price Transparency (DPT) program at the Oregon Department of Consumer and Business Services (DCBS) and publish online. Rebates and payments have an influence on the price of prescription drugs at the pharmacy counter or through health insurance premiums. This additional reporting and online data will allow PDAB to better understand the economic factors involved in drug pricing.

Expand reporting requirements for patient assistance programs:

As currently structured, the DPT program's patient assistance program (PAP) reporting requirements are poorly matched to the market landscape. Currently, only drugs subject to price increase reporting requirements must also report PAP information. PDAB recommends removing the PAP reporting requirement from DPT price increase reports and requiring all manufacturers to report annually on all PAPs they maintain or fund. This collection of more comprehensive data on PAP will provide a more profound and informed analysis to help the DPT program, the board, and the Legislature better understand the roles of patient assistance and co-pay accumulators in developing future policy.

Expand reporting to more insurers for the DPT program:

Currently, 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 (House Bill 4005), these health plans are required to report spending on prescription drugs at the time of the rate filing. Some commercially insured plans (those 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. To improve DCBS and the Legislature's understanding of carrier spending on prescription drugs, the proposal is to separate the rate filing and the drug spending reporting and expand drug spending reporting to all state regulated health insurance carriers in Oregon.

Require patient advocacy organizations to publicly disclose funding sources:

Require patient advocacy groups to disclose their industry funding sources. Understanding these financial ties and potential influences will provide a transparent background for PDAB decisions. The board recommends that patient advocacy groups disclose their industry funding sources publicly for contribution amounts received from third parties, including manufacturers, PBMs, or other groups, and what percentage of the gross income of the organization during the immediately preceding calendar year is attributable to payments, donations, subsidies, or other contributions from each manufacturer, third party, PBM, or group.

Next steps

The board will continue discussing these recommendations and the five options for future study next year. Beginning in 2023, the board will establish affordability review criteria through the public rulemaking process. Once rules are established, PDAB will compile a list of nine prescription drugs and one insulin product for affordability reviews, giving special consideration to health inequities in under-resourced communities. PDAB intends to begin affordability reviews in July 2023.

SB 844, Section 5 Report

Introduction

The Prescription Drug Affordability Board (PDAB) 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 (UPL), pharmacy benefit managers (PBM), and drug patent law. When the Oregon Legislature created the board in 2021, it directed the board to prepare studies and recommendations for the Legislature in 2022 and 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 Drug Price Transparency (DPT) program to compile and provide its first review of nine drugs and one insulin product.

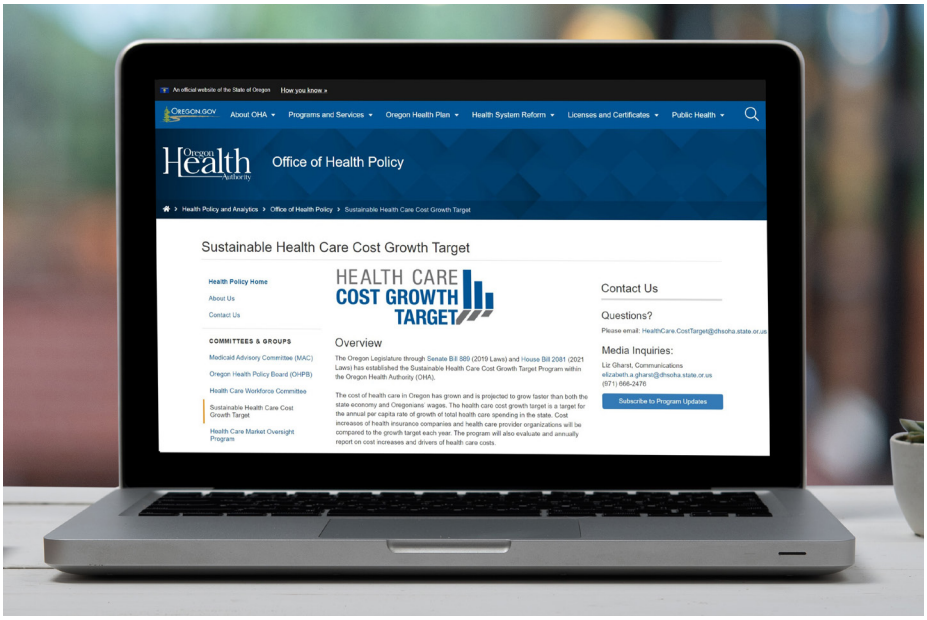
The board has accomplished much in its six months of existence, including studying the drug distribution and payment system and the generic drug market. As a result of these 2022 studies, the board has compiled a list of recommendations for the Legislature to consider to make prescription drugs more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

Overview

PDAB was established under SB 844 and supported by the Department of Consumer and Business Services (DCBS). PDAB aims to protect residents 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 health care economics and clinical medicine. The Senate appointed the board in June 2022, with additional members appointed in September. 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.



six months, including requirements in House Bill (HB) 2993 (2021), 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.

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

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 DPT 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 previously mentioned delays, PDAB will not receive its first quarterly list of drugs for consideration until March 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]

Section 5(2): affordability review

Rulemaking for affordability review criteria must be published before reviews may begin. As the transparent rulemaking process will take four to

Section 5(3): recommendations

For our inaugural reporting requirements, PDAB is submitting consolidated recommendations for the following provisions of Oregon Revised Statutes (ORS):

- 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. PDAB has opted to defer these as optional future study topics 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 PDAB's complete understanding of the issues before consideration for advancement.

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[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.

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

Recommendations for legislative changes

1. 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 cost sharing (co-payment), or the overall impact to the health care system.

This recommendation would require PBMs and group purchasing organizations (GPOs), that operate rebate programs to report information to the DPT program at DCBS. Specifically, PDAB recommends the program be given statutory authority to collect the following information from PBMs and GPOs annually:

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

PDAB recommends 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 or GPO. This additional reporting will allow PDAB and policymakers to more fully understand what influences and contributes to the cost of the drug to the consumer.

2. DPT Program to expand reporting requirements for patient assistance programs

While various aspects of patient assistance programs (PAP) have been discussed in recent legislative sessions, no bills have passed to address their use from either a transparency perspective or their interaction with co-pay accumulators and their effect on the cost to consumers or for the health care system. 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 health care 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 designs that do 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 PAP reporting requirements are poorly matched to the market landscape. Currently, only drugs subject to price increase reporting requirements must also report PAP information. New-to-market-drug reports do not require any PAP reporting, and most price increase reports are for generic drugs, which are extremely unlikely to maintain a PAP.

PDAB recommends removing the PAP reporting requirement from DPT price increase reports and requiring all manufacturers to report annually on all PAPs they maintain or fund. This collection of more comprehensive data on PAP 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.

3. Expand reporting to more insurers for the DPT 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 plans (those 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 proposal is to separate the rate filing and the drug spending reporting and expand the application of the required drug spending reporting to all state regulated health insurance carriers in Oregon.

Optional future study topics

As PDAB convened its inaugural meeting in June, the board had limited opportunities to explore additional complex policy issues and recommendations for consideration. PDAB will consider exploring these topical issues in the future based on member interest and the board's scope of authority, e.g., issues that are governed by or preempted by federal law.

Fee assessments for unsupported price increases

The Institute for Clinical and Economic Review (ICER) produces an annual report/analysis of 10 prescription drugs that significantly affect U.S. health care 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, that 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. The Inflation Reduction Act of 2022 will apply a similar policy to Medicare Part B and Part D drugs. Alternatively, the state policy could impose a penalty on price increases of a certain 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

This proposal would expand the Medicare negotiated price, also called the maximum fair price, as the UPL 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 pass-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 co-pay 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 U.S. Food and Drug Administration-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.

Generic Drugs: *How patents, shortages, contracts, and biosimilars affect the availability and cost*

Introduction

The Oregon Legislature created the Prescription Drug Affordability Board (PDAB) in 2021 and directed the board to conduct a study on the operation of the U.S. market for generic drugs, both dispensed by pharmacists and 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 are nonbranded products that are inclusive of biosimilars and play a crucial role in the U.S. 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 U.S. 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 U.S. 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. In most cases, brand-name drugs have a five-year, exclusivity period, or a seven-year exclusivity period if the drug treats fewer than 200,000 people.[3]

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 U.S. 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

[3] "Exclusivity and Generic Drugs: What Does It Mean?" U.S. Food & Drug Administration. https://www.fda.gov/files/drugs/published/Exclusivity-and-Generic-Drugs--What-Does-It-Mean-.pdf. Accessed Nov. 22, 2022.

and subject to challenge), generic manufacturers are permitted to submit an ANDA. As an incentive to bring generics to market and to 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

Biologic drugs are large complex molecules synthesized in living systems such as bacterial cell cultures making their manufacture more complex than small-molecule drugs made from nonliving chemical ingredients.[4] Biologics are the fastest growing class of therapeutic products in the U.S. and account for a substantial portion of health care costs. They are typically injected, or infused, small-molecule drugs, tablets, capsules, or oral products. Examples of biological drugs are insulin, growth hormone, vaccine, and monoclonal antibodies. There is more variability in the finished biologic product than in a pill or tablet.

Biologic medications and their non-originator analogs (biosimilars) are derived from living systems (e.g., bacteria cell lines) that are inherently more complex. A 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."[5] 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.

Biologics and biosimilars are regulated through distinct approval processes. Biologics also have a similar 20-year patent protection and a period of exclusivity for 12 years after FDA approval.[6] The first biologic market entrant in a class is called the reference product. 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 (BPCIA) created a regulatory pathway for biologics analogous to the ANDA for small-molecule generics, known as the BLA 351(k) pathway. The BPCIA 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. 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.

The adoption of biosimilars in the U.S. 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 percent. Only two biosimilars have an interchangeable designation in the U.S., meaning pharmacists can substitute a biosimilar for the reference product. Biosimilars may be developed for any form of biologic product, including therapeutic proteins such as erythropoietin and insulin, monoclonal antibodies such as Adalimumab (Humira™), and vaccines.

The challenges facing biosimilars entering the market are the same as with the generics. This includes patent litigation and pay-to-delay market entry agreements that are sometimes the product

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[4] 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.

[5] "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.

[6] "Exclusivity and Generic Drugs: What Does It Mean?" U.S. Food & Drug Administration. https://www.fda.gov/files/drugs/published/Exclusivity-and-Generic-Drugs--What-Does-It-Mean-.pdf. Accessed Nov. 22, 2022.

of litigation settlements. Patents on not only the active ingredients but also the manufacturing process and formulations of the drugs create "patent thickets" that protect against the launches of biosimilars. Negotiated formulary exclusivity of the originator product with payers, including Medicare Part D, prevents the uptake of biosimilar utilization.

Generic drug pricing, cost, and utilization

Generic medications are cost-effective alternatives to brand-name medications. Generics represent more than 90 percent of all drugs dispensed annually in the U.S., but they only account for 18 percent of total drug spending, and only 4 percent of overall health care costs.[7] When the market functions correctly, generics are priced 80 percent to 85 percent less than branded counterparts. There are more than 16,000 generic medications available in the marketplace.

The passage 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.[8] 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 percent less than the price of the brand name counterpart when there are more than six competing manufacturers of a particular generic drug.[9] 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. Contributors to this include:

[7] 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.

[8] 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.

[9] 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.

1. Price compression caused by increases in generic competition
2. Limited generic production for medications that have lost patent protection (i.e., after a drug goes off patent, there is a single producer of a generic medication for 180 days)
3. A shortage of raw materials for certain generic drugs that drives up the cost of manufacturing or limits the supply altogether
4. When 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., insurer, self-insured employer, health plan, government program, etc.,) and a pharmacy. The patient cost for generics is typically a small or moderate co-pay. PBMs negotiate rebates, create formularies, process claims, create pharmacy networks, provide drug utilization reviews, and approved drugs to be dispensed at the pharmacy. They also create and administer pharmacy networks and provide mail order and specialty pharmacy fulfillment, many of which are owned by the PBM.[10]

While a patient's cost for generics is typically a small or moderate co-pay, a payor's net cost is based on what the PBM invoices for the generic medication. This invoice is often different from what the PBM reimburses the pharmacy. In some situations, the reimbursement to a pharmacy is less than what it costs the pharmacy to buy and dispense the generic drug to the patient.

In Oregon, state law requires PBMs to disclose to pharmacies the sources used to determine the generic pricing used to reimburse the pharmacy. It also allows pharmacies to challenge the reimbursement it receives.[11]

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 U.S. 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 may be 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).[12] Due

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

[11] Oregon Laws 2022, chapter 735, section 534. (Claim reimbursement.) https://www.oregonlegislature.gov/bills_laws/ors/ors735.html. Accessed Nov. 22, 2022.

[12] "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.

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.

There are no legal requirements for pharmacies to be paid above acquisition cost for generic medications (including ones reimbursed by MAC rates). In the event that a pharmacy cannot purchase generic drugs below the MAC reimbursed rate, they are often left dispensing medications below acquisition cost. In Oregon, for commercial insurance claims, the pharmacy can file a complaint with the Division of Financial Regulation (DFR). In many cases, DFR receives complaints with multiple associated claims, but only a small portion falls within the division's regulatory authority. The division researches the complaint and related claims to establish regulatory authority and sends inquiries to the insurer or PBM.

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 10 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.

Study of generic drugs

Americans spend, on average, $1,300 annually on prescription drugs – more than any other country in the world.[13] 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.[14] These generic pills of the same medication can confuse consumers when the drug is refilled and the pharmacy stocks the product from another manufacturer.

Use of pay-for-delay agreements between manufacturers of brand drugs and their potential generic manufacturer rivals has a significant effect on when and how generic medications become available to consumers. Pay-for-delay deals are agreements between generic and patent-holding pharmaceutical companies, where the patent-holding drug maker compensates the generic manufacturer if the generic manufacturer agrees to refrain from marketing the generic version of a drug past the expiration of the drug's patents, effectively blocking all other generic drug competition.[15] According to an Federal Trade Commission study, these deals cost consumers and taxpayers $3.5 billion in higher drug costs every year.[16]

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 co-pays and premiums for the consumer.

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[13] 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.

[14] "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.

[15] Olivera, Chelsea. "Is the End Near for Pharmaceutical Pay-for-Delay Deals?" University Miami Law Review. https://lawreview.law.miami.edu/pharmaceutical-pay-for-delay-deals/. Accessed Nov. 22, 2022.

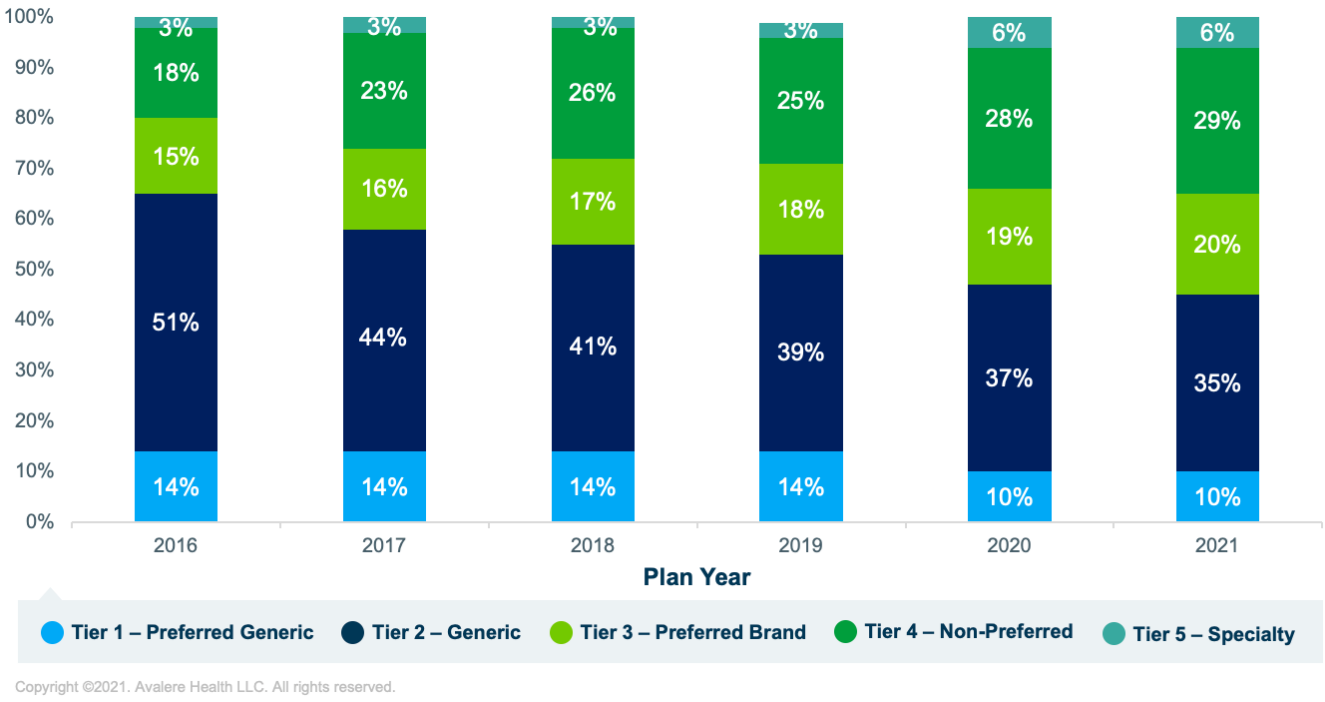
[16] "Pay-for-Delay: When Drug Companies Agree Not to Compete." Federal Trade Commission. https://www.ftc.gov/news-events/topics/competition-enforcement/pay-delay.

A study from the Kaiser Family Foundation that included employer-sponsored health plan formulary design found that only 5 percent of workers in plans with three or more drug tiers had no cost sharing for generic drugs. That figure was 6 percent for workers in plans with just two drug formulary tiers.[17]

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 drug tiers (Figure 1).[18] Specialty drug tiers are known for having co-insurance type cost sharing – a certain percentage of the cost of the drug. It can be as high as 30 percent in Medicare Part D. Figure 2 shows from 2016 to 2021 that generic products were placed on non-generic tiers, which are not designated for generic drugs explicitly, over the five years indicating consumers paying more for medications on the non-generic tier.

Many generic formulations are covered by insurance formularies but may require co-pays, prior authorizations, or alternative step therapies before coverage. Co-payments are the predominant

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

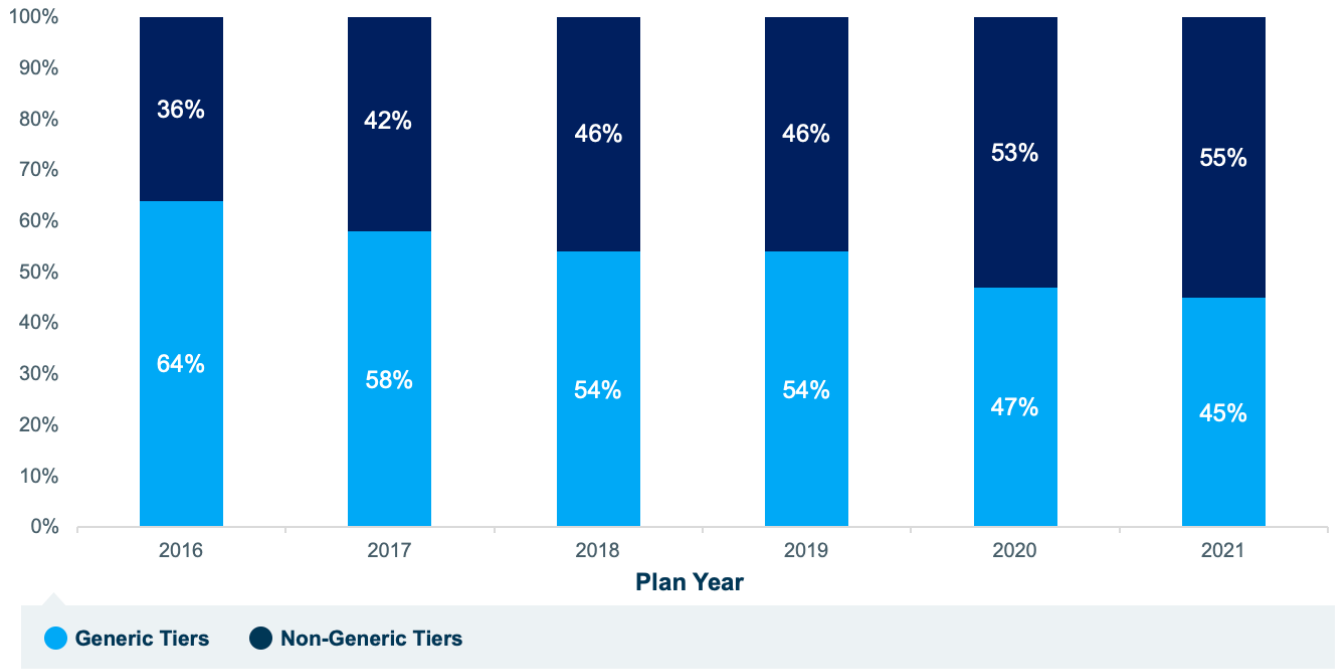


Source: Avalere Health. Accessed Oct. 28, 2022.

[17] "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.

[18] Avalere. "Generic Drug Placement on Part D Generic Tiers Declines Again in 2021," March 11, 2021. https://avalere.com/insights/generic-drug-placement-on-part-d-generic-tiers. Accessed Nov. 1, 2022.

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



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

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 percent) pay less than $10 for generic drugs, but many pay up to $100 co-pay or up to 50 percent co-insurance depending on the generic drug and the formulary tier.[19] Oregon Medicaid has no co-pay 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.[20]

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.[21] Eventually, the organization intends to manufacture these products directly rather than contracting out the manufacturer.

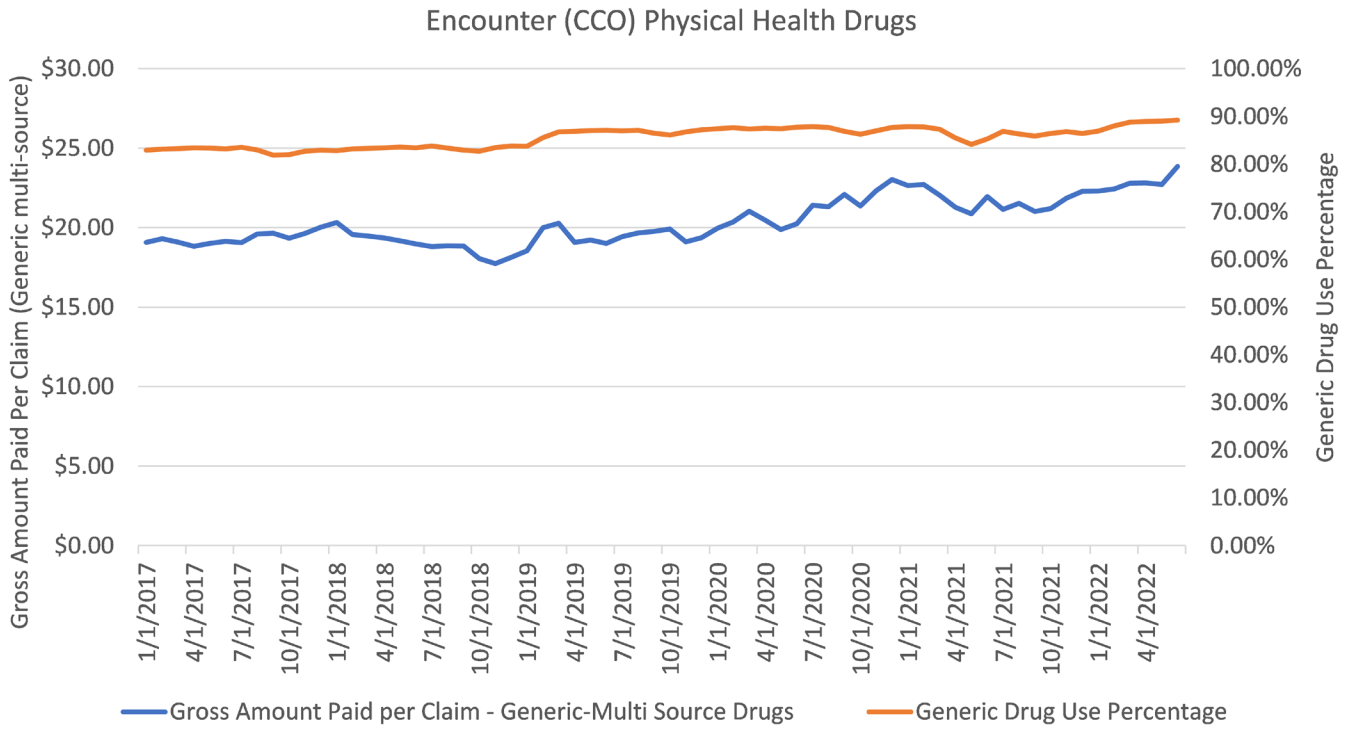
It is impossible to assess precisely the effect of generic drug prices on Medicaid spending because there are thousands of generic drugs and

[19] 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.

[20] 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.

[21] Civica Rx., 2022. https://civicarx.org/. 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.

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.[22]

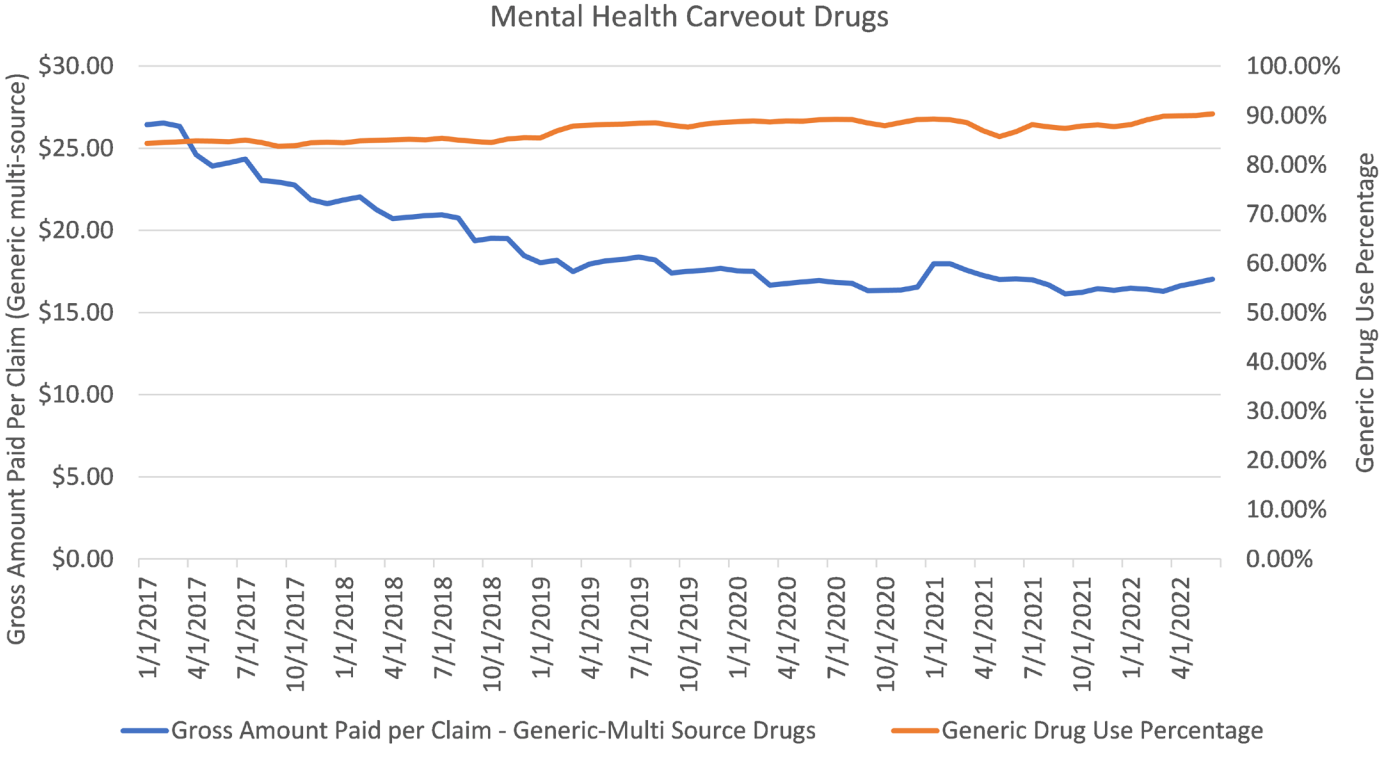
Figure 3 shows the gross amount Oregon Medicaid programs paid per claim on generic-multi source physical health drugs (rebates not subtracted). The figure shows that both the gross amount paid per claim and the generic drug use percentage has gradually increased between 2017 and the first quarter of 2022. Federal and state supplemental drug rebates complicate these utilization trends of the generic multi-source products.

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 from 2017 through the first quarter of 2022 has seen an increase. Utilizing and pricing of mental health drugs are also complicated by using the state's volunteer mental health preferred drug list.

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.

[22] "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 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.

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.[23] 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 may negotiate directly for drug price concessions that lower the net cost of a drug for insurance companies and can also 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 (PAP), and increased rebates for brand drugs for formulary placement to maintain the current

[23] "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.

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.[24]

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 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 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.

Additionally, manufacturers of high-cost brand drugs also offer programs that pay for the start-up and ongoing costs of high-cost drugs such as screening labs, medical tests, first-dose monitoring programs, and ongoing laboratory surveillance. These costs are not covered by the generic or biosimilar manufacturers. Instead, they are charged to insurance companies who pass along the costs to consumers in the form of copays and cost sharing. Any savings from use of a generic or biosimilar for the consumer may be eliminated or worsened by these additional charges.

Nonprofit 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. While the availability of this option will not eliminate the rebate system used by manufacturers to secure placement on payor formularies, a recent partnership with a nonprofit PBM may cause enough market disruption to remove the current incentives for preferred formulary placement by PBMs and health insurers based on manufacturer rebate levels.[25] Still, there is no requirement that the purchasers of Civica Rx drugs pass along savings to patients.

In Europe, they moved much faster to approve biosimilar products to compete on price with reference biologics products. The European Medicines Agency, 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.[26] Notably, a biosimilar only requires evidence of clinical efficacy in one of the reference product's

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[24] "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.

[25] Alston, Maggie, Dieguez, Gabriela, Tomicki, Samantha "A Primer on Prescription Drug Rebates: Insights into Why Rebates are a Target for Reducing Prices." Milliman, May 21, 2018. https://www.milliman.com/en/insight/a-primer-on-prescription-drug-rebates-insights-into-why-rebates-are-a-target-for-reducing. Accessed Nov. 22, 2022.

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

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.[27]

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 U.S. exceeds its supply."[28] They can worsen patient health outcomes based on the need to delay treatment or change treatment regiments, which in some cases can mean substituting fewer effective drugs.

The FDA convened an interagency Drug Shortages Task Force in 2018 that issued a report identifying three root causes for drug shortages.[29] These were:

- Lack of incentives for manufacturers to produce less profitable drugs
- The market not recognizing and rewarding manufacturers for mature quality management systems
- Logistical and regulatory challenges making it difficult for the market to recover after a disruption

The task force concluded that drug shortages – given the fact their effects have been consistently underestimated – likely will continue to persist, absent major changes in the marketplace.[30]

Researchers have estimated that hospitals and health systems spend between $216 million and $359 million in indirect costs and about $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.[31]

In recent years, there have been private market attempts to blunt the impact of generic drug shortages. Civica Rx, a nonprofit drug manufacturer in California, has begun manufacturing drugs in short supply for hospitals and health systems to bring stability, affordability, predictability, and transparency to the generic supply chain.[32] Civica Rx was created to address chronic drug shortages and the uncontrolled price increases of essential generics driven by

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[27] 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.

[28] 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.

[29] "Drug Shortages: Root Causes and Potential Solutions." U.S. Food & Drug Administration, 2019. http://www.fda.gov/media/131130/download. Accessed Nov. 9, 2022.

[30] 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.

[31] Ibid.

[32] "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.

shortages.[33] The Mark Cuban Cost Plus Pharmacy also is ramping up a production facility to manufacture drugs in short supply that will include the sterile filling and packaging of drugs and injectables to help meet short supply demands.[34]

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 passed into law. The law requires the California Health and Human Services Agency 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.[35]

Conclusion

Multiple factors affect the generic drug market. The generic drug industry helps improve prescription medication affordability while maintaining the same safety and efficacy levels of brand-name drugs. Consumers, government programs, and many health care systems support the competition generic drugs provide in the pharmaceutical industry. Yet many challenges exist to getting these drugs to market, including current federal patent laws.

One of the primary purposes of generic drugs is to provide less expensive alternatives to brand-name drugs; however, patents involving drugs and manufacturing affect the entry of generic cost-lowering medicines. Without the competition for generic or biosimilar pharmaceuticals, Americans will continue to spend more on branded drugs. Furthermore, the lack of complete transparency around PBMs and their rebates, discounts, and formularies that provide incentives for the use of branded drugs further disrupts the integration of generic drugs coming to market.

Another challenge generic drug manufacturers face is the supply chain shortage. Shortage of generic drugs constrains the entire health care system, which affects the treatment of consumers. This is partly due to economic factors such as a lack of incentives for manufacturing less profitable drugs, supply chain logistics, and recovery from market disruptions.

Generic drugs are a crucial part of the complex health care system. They provide many benefits to hospitals, providers, pharmacies, insurers, and consumers. However, much work is needed for a generic drug to be a practical part of the health care system.

[33] "Our Essential Medications." Civica. https://civicarx.org/our-medications/. Nov. 9, 2022.

[34] "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

[35] Butler, Johanna. "California Enacts law to Produce Generic Prescription Drugs." NASHP, Oct. 5, 2020. https://www.nashp.org/california-enacts-law-to-produce-generic-prescription-drugs/. Accessed Nov. 9, 2022.

The Prescription Drug Distribution and Payment System:
Understanding the complex process of getting medications from the factory to patients

Introduction and background

In this report, PDAB considers the complexity of how drugs move from the factory to the patient, and how that process affects the cost of prescription medications. The report highlights the prescription drug supply chains for Medicare, Medicaid, and commercial health insurance, and takes a closer look at its effects on patients and prescribers, especially health inequities in diverse communities. The report also reviews policies in other states and countries that potentially lower the cost of prescription drugs before examining reverse auction marketplaces, consolidated drug purchasing, and payor negotiations for Oregon and local governments.

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

Growing Rx cost in the U.S.

The growing cost of prescription medication in the U.S. exceeds all other countries. Other countries spend an average of $550 per capita annually on prescription medications, with the U.S. averaging 2.56 times those in other nations.[36] Between 2008 and 2021, the median launch price for new drugs increased by more than 8,000 percent, from $2,115 to $180,087.[37] During this period, the average list price for new-to-market drugs increased by more than 20 percent a year, which was more than 10 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.[38] Prescription drug spending growth in 2020 increased by 3 percent to $348 billion, which was a slower rate than in 2019 due to "slower overall utilization and an increased use of coupons."[39] Between 2017 and 2021, self-administered cancer drugs had an inflation-adjusted launch price increase of 25.8 percent.[40]

The U.S. Department of Health and Human Services Assistant Secretary for Planning and Evaluation reports the average price increase was about $150 in January 2022 and about $250 in July 2022, with both increases more extensive than the same months in previous years. Also,

[36] 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.

[37] 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.

[38] "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.

[39] "National Health Expenditures 2020 Highlights." Centers for Medicare & Medicaid Services. https://www.cms.gov/files/document/highlights.pdf. Accessed Nov. 9, 2022.

[40] 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.

in 2022, several drugs had list price increases of more than $20,000, or by more than 500 percent.[41] It is projected that over 2023 and 2024, retail prescription drug spending will increase to 4.7 percent and 5.1 percent due to faster price growth and increased utilization.[42]

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.[43] The federal government has not had the ability to negotiate drug prices for Medicare Part D since Congress passed the prescription drug benefit for seniors in 2003. Beginning in 2023, drug companies will be required to pay rebates if drug prices rise faster than inflation. The first negotiated prices would take effect on 10 drugs in 2026, 15 additional drugs in 2027, 15 more in 2028, and 20 more in 2029.[44] Through negotiations and other provisions, the bill is expected to equal net revenue for the government of $288 billion over 10 years.[45]

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. The Inflation Reduction Act sets a $35 monthly cap per prescription for insulin covered by Medicare Part D plans and insulin delivered through traditional pumps. The cap does not apply to patients covered by private health insurance. Beginning in 2024, a 5 percent co-pay on drugs for catastrophic coverage will be eliminated, saving thousands of dollars for patients with serious diseases such as cancer,

[41] "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.

[42] 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.

[43] "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.

[44] Rowland, Christopher. "Drug Industry Poised for Rare Political Loss on Prices." Washington Post, July 28, 2022. https://www.washingtonpost.com/business/2022/07/28/drug-pricing-democrats-manchin/. Accessed Nov. 22, 2022.

[45] "Summary: Inflation Reduction Act of 2022." Senate Democrats. https://www.democrats.senate.gov/imo/media/doc/inflation_reduction_act_one_page_summary.pdf. Accessed Nov. 22, 2022.

hepatitis C, or multiple sclerosis and who require very expensive drugs. In 2025, Medicare enrollees will have an annual out-of-pocket cap of $2,000 for prescription drugs.[46]

Medicare is a federal program, with Part D covering outpatient prescription drugs for people age 65 or older. In Oregon roughly 909,151 people are enrolled in Medicare. There are two types of Part D plans available.[47] Standalone plans cover only prescription drugs that 265,609 Oregonians are enrolled in and Medicare Advantage plans that cover prescription drugs and provide other Medicare benefits. Another 444,899 Oregonians are enrolled in Medicare Advantage prescription drug (MA-PD)plan. The Kaiser Family Foundation reports the following estimated impact on Oregon Part D beneficiaries:[48]

Drug prices for each type of Medicare plan are determined by negotiations between plans (or their pharmacy benefit managers (PBM) and manufacturers. Figure 1 illustrates Medicare's purchasing system for outpatient prescription drugs. The Center for Medicare and Medicaid Services (CMS) provides subsidy and reinsurance into the Part D plan.[49] Additionally, 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. PBMs 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 may pay post-point-of-sale price concessions to PBMs 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. These charge-backs often exceed 5 percent of the total amount a PBM paid a pharmacy for a drug. This is

Eliminates 5% co-insurance above the Part D catastrophic threshold	Establishes the $2000 out-of-pocket spending cap for Part D	Expands income eligibility for full Part D low income subsidies	Eliminates cost sharing for adult vaccines covered under Part D
14,190	20,360	5,300	69,440

[46] Cubaniski, J., Neuman, T, Freed, M., and Damico, A. "How Would the Prescription Drug Provisions in the Senate Reconciliation Proposal Affect Medicare Beneficiaries?" Kaiser Family Foundation, July 27, 2022. https://www.kff.org/medicare/issue-brief/how-would-the-prescription-drug-provisions-in-the-senate-reconciliation-proposal-affect-medicare-beneficiaries/. Accessed Nov. 22, 2022.

[47] Norris, Louise. "Medicare in Oregon: Oregon has strong protections for Medigap enrollees; nearly half of Medicare beneficiaries in Oregon have Medicare Advantage plans." HealthInsurance.org, Sept. 22, 2022. https://www.healthinsurance.org/medicare/oregon/. Accessed Nov. 22, 2022.

[48] Cubaniski, J., Neuman, T, Freed, M., and Damico, A. "How Would the Prescription Drug Provisions in the Senate Reconciliation Proposal Affect Medicare Beneficiaries?" Kaiser Family Foundation, July 27, 2022. https://www.kff.org/medicare/issue-brief/how-would-the-prescription-drug-provisions-in-the-senate-reconciliation-proposal-affect-medicare-beneficiaries/. Accessed Nov. 22, 2022.

[49] "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.

not 5 percent of profit, but 5 percent of the total reimbursed amount. These DIRs are charged up to 180 days after the time the drug is dispensed and results in pharmacies nationwide often filling prescription medications far below acquisition cost. Many pharmacies are starting to leave Part D networks due to this, which results in accessibility issues for Oregonians. DIR fees can also penalize pharmacies depending on how they are applied.

DIRs were established to help control Medicare program expenses and premiums, but they do 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 DIR showed nearly a 14 percent per year increase between 2010 and 2015.[50] Increasing DIR levels means higher out-of-pocket spending for enrollees and increasing costs for the government.[51] The fees negatively impact pharmacies, especially independently owned or community based, because the fees are unpredictable and are not known at the time of the prescription transaction. Due to the lack of transparency and clawbacks, it is challenging to account for DIRs or for pharmacies to amend contracts with PBMs. Figure 2 provides a general overview of this trend.

Prescription drug supply chain for Medicaid

CMS defines Medicaid as a federal program, working with states, to pay for medical assistance for people in tremendous economic need. All state Medicaid programs provide coverage for outpatient

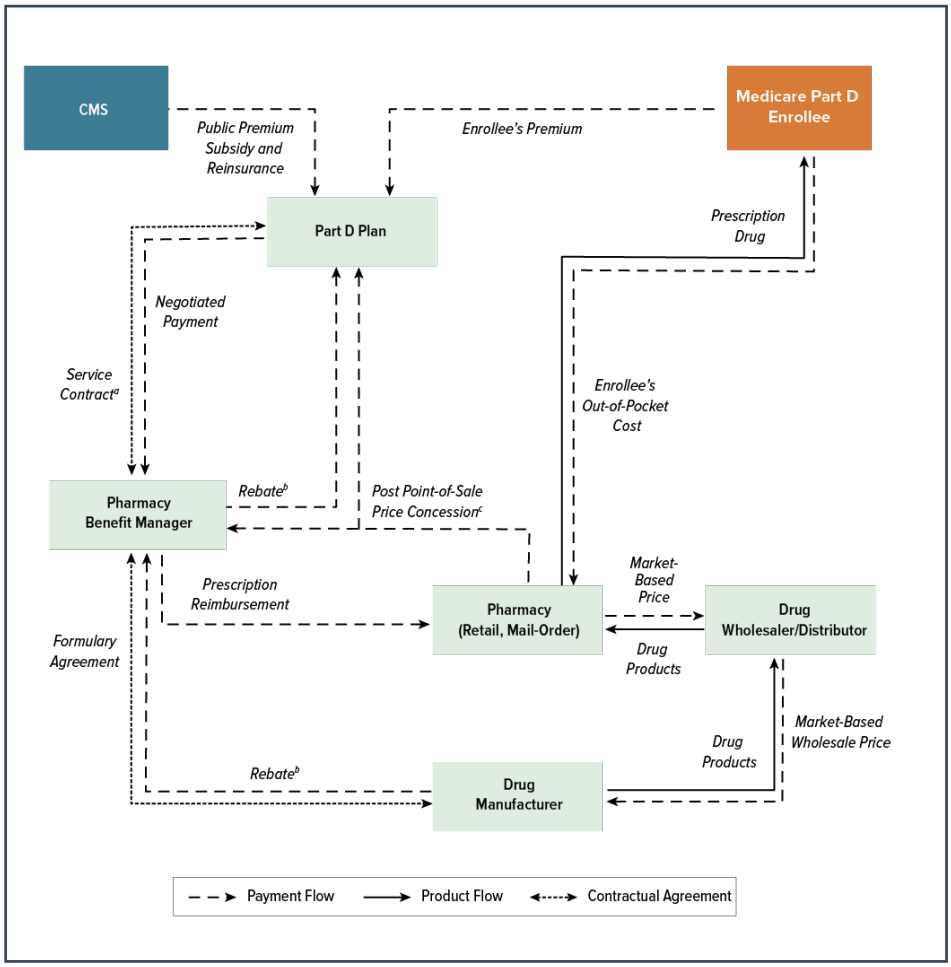


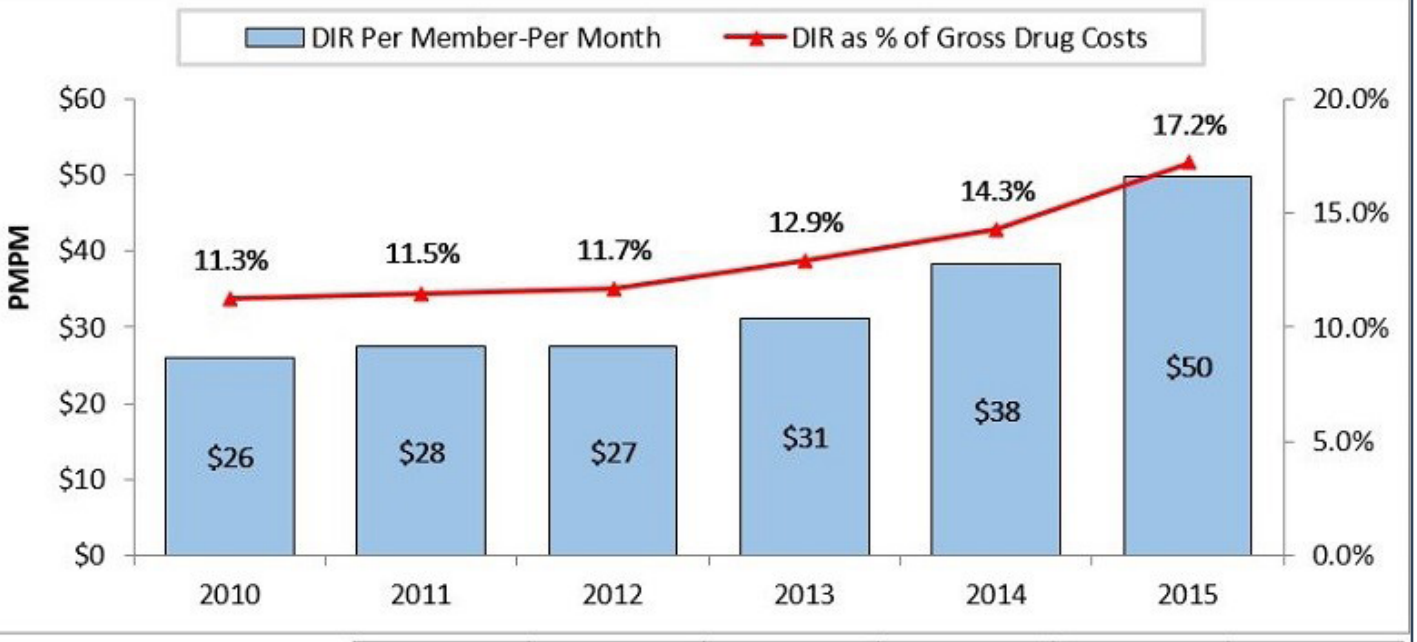
Figure 1: Medicare Part D's system for purchasing brand-name outpatient prescription drugs.

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.

[50] "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.

[51] Ibid.

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 drugs, though pharmacy coverage is optional under federal Medicaid law.[52] As of July 2022, Oregon has enrolled 1,331,443 individuals in Medicaid and Children's Health Insurance Program (CHIP), a net increase of over 112 percent since 2013.[53] Oregon is one of 15 states that does not impose cost sharing on beneficiaries for prescription drugs.[54]

In a 2020 Issues Brief, the Kaiser Family Foundation looked at Medicaid's overall prescription drug prices, changes to federal rules in 2016, and the resulting reliance on PBMs and related effects on state programs.[55] They found that the price Medicaid pays for drugs results from a complex set of factors and inputs, which diagrams in Figure 3.

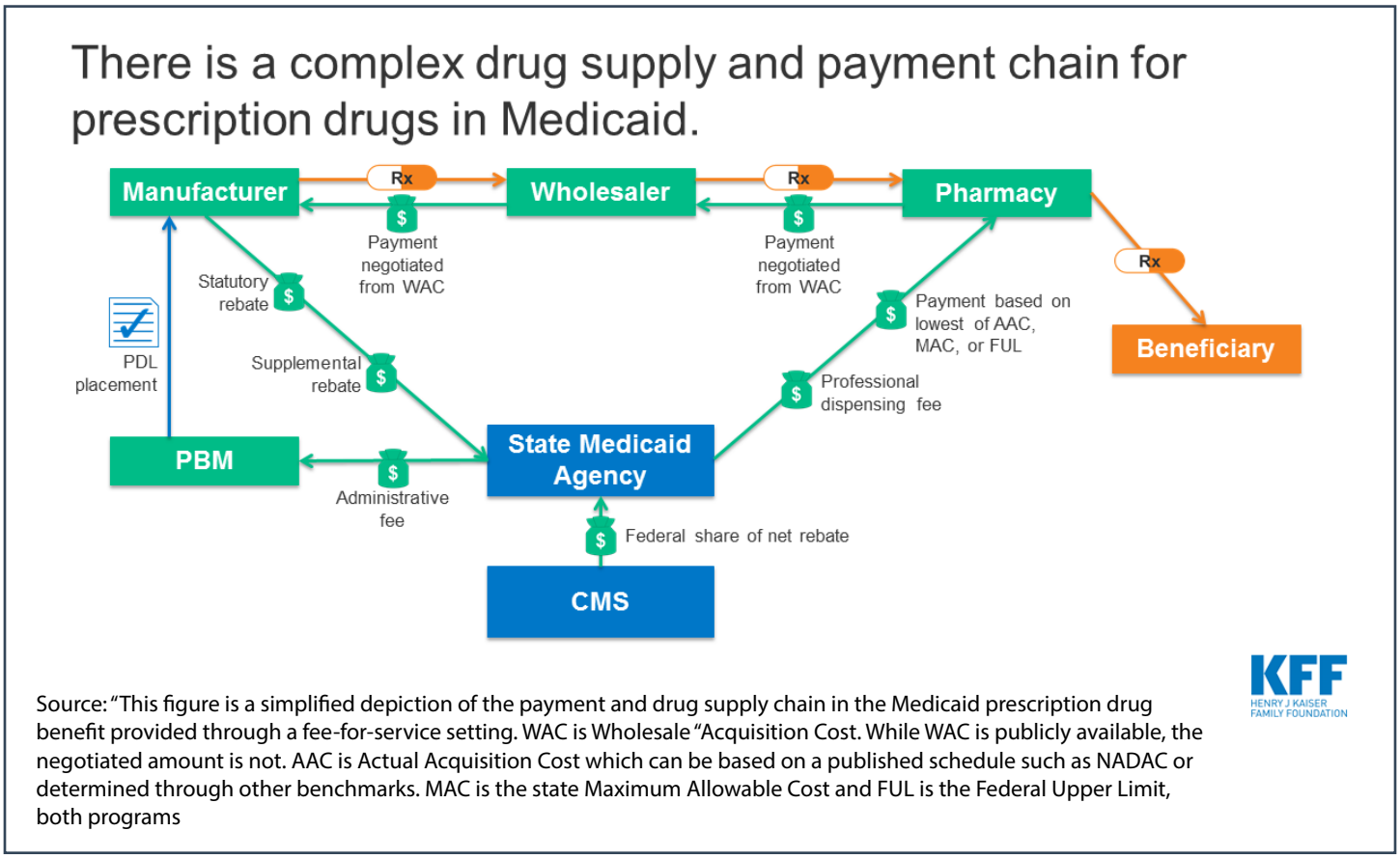
[52] "Prescription Drugs." Centers for Medicare & Medicaid Services, U.S. Department of Health and Human Services. https://www.medicaid.gov/medicaid/prescription-drugs/index.html. Accessed Nov. 4, 2022.

[53] "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.

[54] "Medicaid Benefits: Prescription Drugs." Kaiser Family Foundation, 2018. https://www.kff.org/medicaid/state-indicator/prescription-drugs. Accessed Nov. 7, 2022.

[55] 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

The 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 any rebates, to the state Medicaid agency. State Medicaid programs then reimburse pharmacies for prescription drugs based on the cost of the ingredients as well as a dispensing fee. It is important to note, Medicaid agencies do not buy drugs directly from manufacturers; they reimburse pharmacies that fill prescriptions written for Medicaid enrollees. According to the Kaiser Family Foundation, "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 (MCO), MCOs reimburse the pharmacy, typically through a PBM."[56]

MCOs in Oregon operate as coordinated care organizations (CCO), which are local organizations that provide health service benefits through the Oregon Health Plan (OHP), the state's Medicaid program. There are 16 CCOs providing services to OHP members, and their plan arrangements include prescription drugs as a covered benefit, with some exceptions for mental health drugs. The CCOs are reimbursed under a capitated rate consistent with federal law. Certain drugs are "carved out" as part of a risk mitigation strategy similar to other states.[57] Specifically, Oregon Administrative Rules on Medical Assistance Programs (Chapter 410) state

[56] Ibid.

[57] Gifford, Kathleen, et al. "How State Medicaid Programs Are Managing Prescription Drug Costs: Results from a State Medicaid Pharmacy Survey for State Fiscal Years 2019 and 2020." Kaiser Family Foundation, Report, April 2020, https://www.kff.org/report-section/how-state-medicaid-programs-are-managing-prescription-drug-costs-pharmacy-benefit-administration. Accessed Nov. 18, 2022.

that CCOs shall pay for covered prescription drugs, except for the following:[58]

- Mental health drugs, including ataractics-tranquilizers and psychostimulants-antidepressants
- Depakote, Lamictal, and their generic equivalents
- Drugs covered under Medicare Part D when the member is fully dual eligible
- Prescriptions for physician assisted suicide under the Oregon Death with Dignity Act

In Oregon, actual acquisition cost (AAC) surveys and the 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 a tier structure based on the annual volume of prescriptions filled, ranging from $9.68 to $14.01. CCOs reimburse pharmacies for their beneficiaries' prescriptions based on their contracts with PBMs. These contracts specify guaranteed discounts on ingredient costs and maximum dispensing fee costs.

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, net of rebate 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 the Kaiser Family Foundation, PDLs often include lower-cost drugs or drugs for which a manufacturer has provided supplemental rebates, as PDL placement is a primary lever states use to negotiate supplemental rebate agreements. The manufacturer then provides the drugs to a wholesaler, who 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 (WAC).

Medicaid prescription drug programs are subject to a unique rebate program administered by CMS. The program was created under the Omnibus Reconciliation Act (OBRA 1990). It requires all drug manufacturers wanting to have their products covered by Medicaid to enter into an agreement with the U.S. Department of Health and Human Services secretary to provide a rebate to the federal government to help fund the Medicaid program. Participation in this program is also mandatory for manufacturers to participate in the 340B program and enter into an agreement with the U.S. Department of Veterans Affairs.[59] "By statute, the rebate amount ensures the Medicaid program gets the lowest price (with some exceptions)."[60]

Medicaid drug rebates are a complicated and highly confidential amount that are not subject to public disclosure. They include a number of conditioning factors, including the length of time a manufacturer has been in the program, an inflationary adjustment, and other variables.

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[58] Oregon Health Authority, Health Systems Division: Medical Assistance Programs. Oregon Administrative Rule 410-141-3855 (2022). https://secure.sos.state.or.us/oard/viewSingleRule.action?ruleVrsnRsn=287587. Accessed Nov. 21, 2022.

[59] "Medicaid National Drug Rebate Agreement (NDRA)." Centers for Medicare & Medicaid Services, April 26, 2022. https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/medicaid-national-drug-rebate-agreement-ndra/index.html. Accessed November 22, 2022

[60] Dolan, Rachel. "Understanding the Medicaid Drug Rebate Program." Kaiser Family Foundation, Nov. 12, 2019. https://www.kff.org/medicaid/issue-brief/understanding-the-medicaid-prescription-drug-rebate-program/ Accessed November 22, 2022.

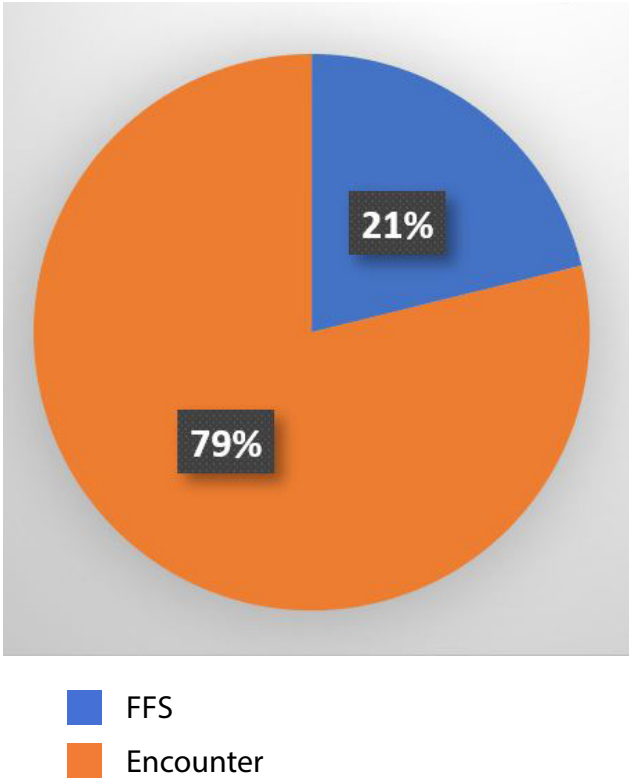
Generally, rebates for brand-named drugs with high costs are significantly lower than other branded drugs.[61] Rebates are paid on a quarterly basis, based on utilization files submitted by states.

The Affordable Care Act (ACA) increased rebate amounts for generic and branded products while also extending rebates for utilization by managed care enrollees, which are operated as CCOs in Oregon. While increases in federal rebate amounts increased, the percentage retained by states remains the same prior to passage of the ACA, meaning a larger amount is retained by the federal government. Oregon utilizes a contractor for rebate invoicing and dispute resolution for its fee-for-service utilization and rebates for CCO utilization.

State supplemental rebates are negotiated by states in addition to federal rebates to lower the net cost of drugs and to identify those that are the most safe, efficacious, and cost effective. It is this mechanism that creates situations where branded products are on a state's PDL. A portion of state supplemental rebates must also be remitted back to CMS. Based on the manufacturer's interest and will to pay for product placement on a PDL, situations arise where branded products are less expensive to the state than generics. Additionally, CCOs can also negotiate their own rebates with manufacturers through their contracted PBMs.

Oregon has a PDL 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, OHP. The database is not a statewide PDL. In Oregon, nonpreferred physical health drugs, for example, those not on the PDL, are subject to prior authorization, whereas nonpreferred 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 CCO 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. Figure 4 highlights the percent of drugs dispensed by volume in Oregon on fee-for-service Medicaid compared to CCO encounters.

Figure 4: FFS (free for service) and CCO drugs dispensed by volume



Source: Oregon State University Drug Use Research and Management. https://www.orpdl.org/durm/reports/utilization/2022/DUR_Utilization_2022_Q2.pdf. Accessed Nov. 22, 2022.

[61] Park, Edwin. "New MACPAC Data on the Highly Effective Medicaid Drug Rebate Program." Georgetown University Health Policy Institute, Nov. 3, 2022. https://ccf.georgetown.edu/2022/11/03/new-macpac-data-on-the-highly-effective-medicaid-drug-rebate-program/. Accessed November 22, 2022.

Prescription drug supply chain for commercial insurance

Similar to the Medicare and Medicaid distribution and payment systems, commercial insurance negotiates for payment and distribution of brand-name and generic drugs through similar structures (Figure 5). However, instead of CMS funding a specific health plan, employers and beneficiaries pay premiums to contracted health plans that negotiate with PBMs on covered pharmacy costs. Pharmacies also negotiate the price for drugs with wholesalers who distribute drugs produced by manufacturers. The average manufacturer price (AMP) 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 pharmacy benefit managers (PBM), or directly with insurers, for product placement on their formularies to meet the needs of employer-sponsored benefit programs.

Although the distribution system seems straightforward, many components affect cost 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 U.S. are independently owned or community based.[62] Because community pharmacies are typically independent (or owner operated), or comprised of smaller regional chains, their ability to compete with larger national chains makes business viability challenging, especially when faced with price concessions from PBMs as a condition to participate in their pharmacy networks. 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."[63] 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." It was reported that the independent pharmacy lost money due to the PBM, which managed the county's drug benefits plan.

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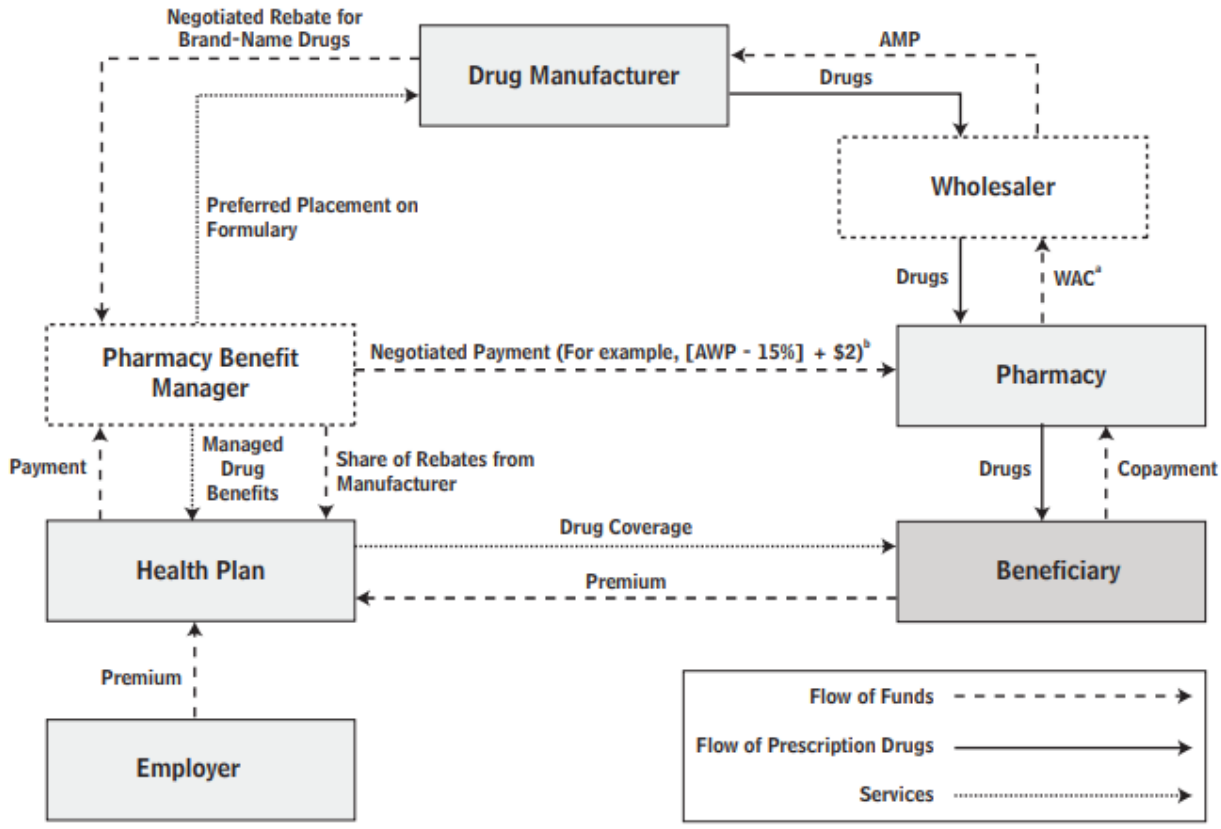
[62] "Competition, Consolidation, and Evolution in the Pharmacy Market." Controlling Health Care Costs, Issue Briefs, Aug. 12, 2021. https://www.commonwealthfund.org/publications/issue-briefs/2021/aug/competition-consolidation-evolution-pharmacy-market. Accessed Nov. 4, 2022.

[63] 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.

Figure 5: 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. The program is intended to assist providers in the health care safety net with lowering the cost of medications for underserved communities. It is managed by the U.S. Health Resources and 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 percent to 50 percent. In 2020, estimated discounted drug purchases through the 340B program amounted to roughly 7 percent of the total U.S. drug market.[64] The program, as created by Congress, is intended to enable qualified or covered entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing comprehensive services.[65] In the calendar year 2021, 340B-covered

[64] "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.

[65] "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.

Figure 6: 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.

entities purchased $43.9 billion in outpatient drugs under the 340B Program, shown in Figure 6.[66]

These safety net providers include Federally Qualified Health Centers (FQHCs), Rural Health Centers (RHC), tribal and urban Indian Health Centers (IHC), 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 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.[67] Section 340B covered entities can generate profits by prescribing drugs to patients

[66] "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.

[67] 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.

with private insurance or Medicare. Those 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.[68]

For many years, criticism was centered around hospitals. In 2013, Sen. 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."* [69]

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.[70]

For a drug to be eligible to receive a 340B program price, the covered entity must demonstrate that the patient received care from an eligible 340B prescriber. This has become increasingly challenging as covered entities have relied on retail pharmacies to dispense medications.

The increasing use of retail pharmacies by covered entities has made it difficult to validate whether an individual receiving a prescription at a retail pharmacy is in fact eligible to receive the drug using the 340B program price. This has led to charges that 340B prices are being extended to patients who are in fact ineligible to participate in this program.

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.[71] 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 (for example, not use 340B drugs for Medicaid patients) unless the covered entity has an arrangement with the state Medicaid agency to prevent duplicate discounts.[73] 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 16 drug manufacturers have said they will limit or halt discounts to safety net hospitals for drugs dispensed at community-based pharmacies.[73]

Providers state that any effort to limit the use of contract pharmacies violates 340B statutes and

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[68] Ibid.
[69] Ibid.
[70] "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.
[71] "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.
[72] "Contract Pharmacy Services." Health Resources & Services Administration, June 2022. https://www.hrsa.gov/opa/implementation-contract. Accessed Nov. 8, 2022.
[73] 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.

HRSA guidance. The Biden administration has reviewed the measures drug manufacturers are imposing on providers and determined their actions are in violation of the law, resulting in 340B entities paying more than the discounted price they are eligible to receive.[74]

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

About nine in 10 prescriptions that are dispensed are generic. (For the purpose of this report, the term "generics" includes nonbranded multi-sourced products and biosimilars.) Nevertheless, the amount spent on prescription drugs has only accelerated, as the generic supply chain has become more limited and manufacturers have created rebate incentives with PBMs. Because there is limited marketing for generic manufacturers, patients are not always best positioned to understand that generic drugs are of equal therapeutic value. Given the use of co-pay 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 compounded by insurance formularies or preferred drug lists (PDL). 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 authorization as a cost containment strategy. Prior authorization 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 may impact or delay patient care. According to a survey by the American Medical Association, 88 percent of the 1,004 health professionals surveyed reported a high burden due to prior authorization.[75] The average number of prior authorizations per week was 41, taking roughly 13 hours to complete. The same survey found that 93 percent of physicians reported that prior authorizations caused 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 prior authorization can be used to manage prescription drug costs, it also improves patient outcomes. The intent of prior authorization is to ensure that drug therapy is medically necessary, clinically appropriate, and

[74] "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.

[75] "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.

aligns with evidence-based guidelines. Research by the Academy of Managed Care Pharmacy has concluded, "a well-designed, evidence-based prior authorization program optimizes patient outcomes by ensuring that patients receive the most appropriate medications while reducing waste, error and unnecessary prescription drug use and cost."[76]

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.[77] Payors spend about $6 billion annually administering drug utilization management, and manufacturers spend about $24.8 billion supporting patient access in response. Physicians devote almost $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 co-pay coupons or co-pay 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. Co-pay coupons, may also serve as a marketing tool for manufacturers to improve market share as many of the drugs that manufacturers use patient assistance programs (PAP) or co-pay cards for are single-source therapies with no equivalent generic version or therapeutic alternative. Drug manufacturers use them to steer insured patients toward their medication. This can circumvent payer strategies that steer patients to the most clinically and cost-effective option because the use of a co-pay coupon can mean the patient may not have a financial incentive to use a lower-cost preferred therapy.

Fifteen states have passed laws that require PBMs and payers to include co-pay assistance in the calculation of patient cost-sharing limits. More than 15 million Americans representing about 11 percent of the U.S. commercial insurance market are enrolled in plans that are required to count any form of co-pay assistance toward cost-sharing limits.[78] Oregon does not have a law prohibiting the use of co-pay accumulators.

Patients with no or limited insurance can be referred to a 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 co-pay coupon and PAP are programs to help patients afford their medications, these programs do little to reduce the cost of prescriptions overall or make them affordable for the health care system.

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

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[76] "What is Prior Authorization and Why is it an Essential Managed Care Tool?" Concept Series, Academy of Managed Care Pharmacy, July 18, 2019. https://www.amcp.org/about/managed-care-pharmacy-101/concepts-managed-care-pharmacy/prior-authorization. Accessed Nov. 21, 2022.

[77] 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.

[78] "State Copay Accumulator Bans Impact 11% of US Commercial Lives." Avalere Health, Nov. 11, 2022. https://avalere.com/insights/state-copay-accumulator-bans-impact-11-of-us-commercial-lives. Accessed Nov. 22, 2022.

Due to high co-pays, 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 Northwestern University research summary.[79] Researchers at Harvard and UCLA have found coupons for brand-name drugs facing generic competition boosted retail sales by more than 60 percent and increased spending between $30 million and $120 million per drug during the five-year study period. This translated to as much as a $2.7 billion increase in spending for the 23 drugs studied.[80] 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 percent per year versus 7-8 percent for branded drugs without coupons.[81] Another adverse effect in many states, including Oregon, is that manufacturer coupons do not count toward the high out-of-pocket maximums that many patients have with their insurance.[82]

Nonprofit pharmaceutical companies like Civica Rx might be able to lower list prices of drugs and sell directly to large purchasers like the U.S. Department of Veterans Affairs and hospital systems.[83] They would not eliminate the rebate system used today by health insurance companies and PBMs. However, they may cause enough market disruption to cause PBMs and insurance companies to rethink their pricing and reimbursement strategies. Still, there is no requirement to pass along any savings to patients.

An additional component in the drug supply chain is the distribution of medications at hospitals or physician offices. There are a number of ways hospitals and medical offices acquire physician administered drugs. This includes direct from the manufacturers, through wholesalers, group purchasing organizations (GPO), or local pharmacies.[84] Hospitals and physician practices are often members of GPOs that negotiate discounts off product wholesale prices.[85] Medications dispensed at a physician's office are covered under the medical benefit and not through pharmacy benefits. Inpatient hospital pharmacies are similar to the outpatient model, although the insurer payment structure is different. Pricing for physician-administered drugs are determined by 1) the actual acquisition cost (AAC), 2) the wholesale acquisition cost (WAC), 3) the average wholesale price (AWP),

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[79] 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.

[80] Ibid.

[81] 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.

[82] "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.

[83] 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. 2022.

[84] "Physician-Administered Drugs: Distribution and Payment Issues in the Private Sector." MedPAC, NORC at the University of Chicago, No. 03-4, August 2003. https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/contractor-reports/Aug03_DrugsDist-cont-Rpt.pdf. Accessed Nov. 22, 2022.4, 2022.

[85] Mulcahy, Andrew, Vishnupriya, Kareddy. "Prescription Drug Supply Chains." Rand Corporation, 2021. https://aspe.hhs.gov/sites/default/files/documents/0a464f25f0f2e987170f0a1d7ec21448/RRA328-1-Rxsupplychain.pdf. Accessed Nov. 22, 2022.

and 4) the Medicare allowable cost, which pays an average sales price (ASP) plus a margin.[86]

Health inequities in diverse communities

Pharmacy reimbursement commonly delegated to PBMs on behalf of health plans, can create financial stress on local, independently owned or community-based pharmacies. Independently owned and community-based pharmacies are more likely to serve rural and inner-city communities that are already underserved by the health care system. In 2021, GoodRx identified eight Oregon counties where 100 percent of the population lives more than 15 minutes from the three closest pharmacies. In January of 2022, a retail chain in Oregon, Bi-Mart, stopped providing pharmacy services, "citing increase costs and ongoing reimbursement pressures."[87] The closing of Bi-Mart's pharmacy services affected many rural areas in Oregon as it was often the only pharmacy in the area, further affecting access issues.

Increased drug costs, the evolution of the PBM role, and changes in PBM reimbursement strategies have led to a loss of independent pharmacies in Oregon and most other states.[88] 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 health care system. When independent pharmacies disappear, access to care in already underserved communities declines even further. There are about 50 communities in Oregon where the closest pharmacy is at least 15 miles away from town. Another view is that between 2003 and 2018, 10 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.

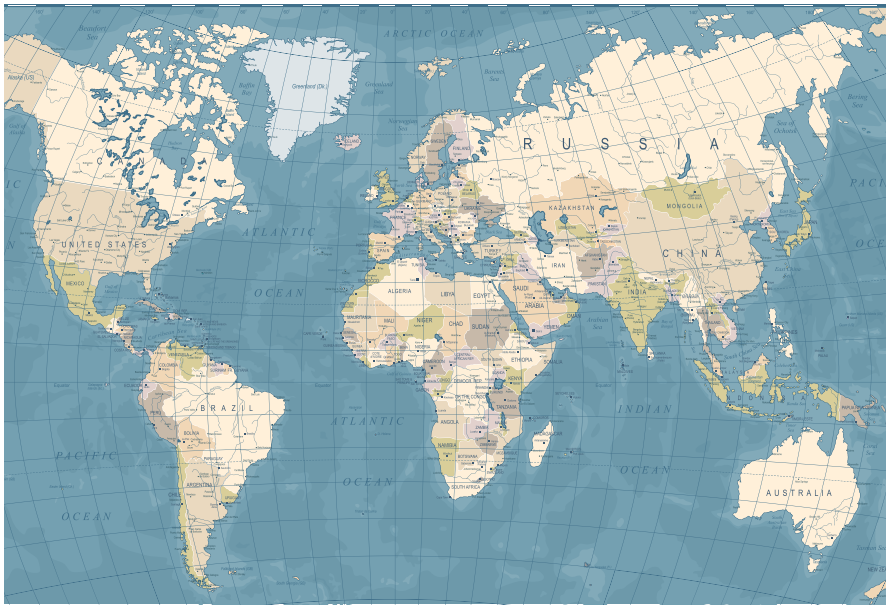
The pharmacy benefit design of many public and private health plans can create or exacerbate medical debt in the underserved, even among people with insurance. Based on the complex issues and systems described in this report, people often struggle to pay for their prescriptions. Multiple

[86] "Physician-Administered Drugs: Distribution and Payment Issues in the Private Sector." MedPAC, NORC at the University of Chicago, No. 03-4, August 2003. https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/contractor-reports/Aug03_DrugsDist-cont-Rpt.pdf. Accessed Nov. 22, 2022.

[87] "Understanding Pharmacy Reimbursement Trends in Oregon." Three AXIS Advisors. Oct. 27, 2022. https://www.3axisadvisors.com/projects/2022/10/27/understanding-pharmacy-reimbursement-trends-in-oregon. Accessed Nov. 22, 2022.

[88] 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.

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 or health care 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 nonadherence. Many Medicare Part D and employer plans apply co-insurance cost sharing for very high-cost drugs, which is a percentage of the drug cost rather than a flat co-pay amount. This is done to incentivize individuals to use lower-cost options. 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 health care needs.



A Brookings Institution report notes that Black, Latino or Hispanic, American Indian, and Alaska Native people are less likely to have medical insurance and are more likely to go into medical debt and suffer avoidable medical morbidity.[89] Often, households of color go without insurance and are nearly twice as likely to hold medical debt than households with insurance (28 percent versus 17 percent, respectively).[90] Understanding socioeconomic status, geographic access to health care services and health insurance coverage will help reduce inequities in underserved and disadvantaged communities.

Policies in other states and countries to lower Rx

The U.S. pays significantly more for prescription drugs than other industrialized countries.[91] According to the Organization for Economic Cooperation and Development (OECD), the U.S. spent $1,376 per capita on prescription drugs – more than twice the average across other OECD countries ($571).[92] Pharmaceutical spending in the U.S. was 47 percent higher than in Germany, 70 percent higher than in Canada, 108 percent higher than in Australia, and 198 percent higher than in the United Kingdom. Aggregate pharmaceutical spending is a function of product mix, volume, and price. Although the U.S. is an outlier with respect to net pharmaceutical spending, it is not appreciably higher in terms of overall prescribing.

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[89] 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.

[90] Ibid.

[91] 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.

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

A 2017 survey of older adults in 11 industrialized countries reported that 55 percent of older adults in the U.S. used four or more prescription drugs compared to 47 percent in the United Kingdom, the next highest country.[93] The U.S. also leads the world in generic drug utilization.[94] Thus, excess pharmaceutical spending in the U.S. is primarily a function of higher prices.

Most industrialized countries have a centralized health care authority that makes health care financing and delivery vastly more efficient. The specific approach that nations use to purchase pharmaceuticals may differ, but most share a similar feature in that the health care authority sets prices or has broad authority to restrict coverage based on cost or value.[95] Even as industrial countries select strategies that focus on lowering the cost of medications based on their approaches, in some cases, this results in less choice among consumers. Summarized below is a brief description of pharmaceutical reimbursement in four, high-income, industrialized nations similar to the U.S.

United Kingdom: The National Health Service (NHS) provides health care in the United Kingdom. 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 to determine 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.[96]

Canada: Similar to the United Kingdom, Canada has a single, publicly funded health care system (Health Canada).[97] However, outpatient pharmaceuticals are not included in the federal health insurance program and are covered by each individual province or territory that defines eligibility criteria, coverage, and reimbursement formulas. Provincial and territorial governments rely on health technology assessments processed through the Common Drug Review (CDR) to provide syntheses of clinical and cost-effectiveness data along with recommendations for coverage. While individual drug plans are not required to follow CDR coverage

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[93] 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.

[94] 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.

[95] 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.

[96] 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/. Accessed Nov. 7, 2022.

[97] 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.

recommendations, they do 90 percent of the time.[98] 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 nongovernmental sickness fund along with optional private insurance.[99] Similar to the United Kingdom, Germany relies on a formal evaluation of a new drug's value by the Institute for Quality and Efficiency in Health Care (IQWiG).[100] IQWiG synthesizes 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 nongovernmental 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, the new drug is reference priced to those therapies.

Australia: Australia has a single-payer, federally funded health care system with prescription drug coverage provided to all citizens through the Pharmaceutical Benefits Scheme (PBS).[101] 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.[102] 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.

Upper payment limits (UPL)

An upper payment limit (UPL) is the maximum amount that can be paid or billed for a prescription drug that is dispensed or distributed in any financial transaction concerning the purchase or reimbursement of a prescription drug. UPLs are not a new phenomenon in government purchasing of prescription drugs. The Medicaid program, a partnership between states and the federal government used federal upper limits (FUL) in Medicaid prescription drug reimbursement for decades prior to adoption of the National Drug Acquisition Cost (NADAC).[103] The basic premise of Medicare's ability to negotiate prescription drug prices drug prices, provided through enactment

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[98] 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.

[99] 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.

[100] 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.

[101] 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.

[102] 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.

[103] Center for Medicare & Medicaid Services; Federal Upper Limit; Affordable Care Act Federal Upper Limit. https://www.medicaid.gov/medicaid/prescription-drugs/federal-upper-limit/index.html. Accessed November 22, 2022Accessed Nov. 7, 2022.

of the Inflation Reduction Act, is a UPL for the negotiated price of a given single-source brand-name drug ("maximum fair price"). This limit for a Part D drug is the lower of a drug's enrollment-weighted negotiated price, net of all price concessions, the average sales price for a Part B drug, or a percentage of a drug's average non-federal average manufacturer price.[104]

A statewide UPL leverages the current operations of the supply chain. According to a recent health policy report, "The UPL uses the standard operating procedures of the existing supply chain where supply chain participants negotiate price concessions and those negotiated price concessions are fulfilled by wholesalers."[105] Operationally, this does not regulate how manufacturers list or set prices. Manufacturers commonly adjust their price concessions through negotiations with PBMs and wholesalers when payer reimbursement does not cover the product list price, e.g. WAC. "The point of an UPL is to expand sales and patient access. The purpose is not to reduce manufacturer revenue for a drug."[106]

Currently, only two states have statutory authority to set UPLs that charge their PDABs to set UPLs through administrative rulemaking. Maryland will begin rulemaking on its UPL methodology in calendar year 2023 following its completion of drug affordability reviews. The Maryland program is required by statute to evaluate whether it is in the best interest of the state to establish a UPL-rate-setting methodology for drug products that create affordability reviews and develop an action plan to implement.[107]

Colorado's legislation requires their PDAB to set upper payment limits on drugs it has deemed unaffordable. Statute allows it to set UPLs for a maximum of 12 drugs per year for the first three years. The Colorado PDAB is working with its advisory committee and stakeholders in both affordability criteria and UPL methodology development.[108]

UPLs can also have accountability measures to ensure savings are used to lower overall health costs for both consumers and insurers. Colorado's UPL statute requires health benefit plans to document how any savings attributable to the UPL are used to reduce costs for consumers, prioritizing the reduction of out-of-pocket costs for prescription drugs.[109]

UPLs would more easily allow consumers to understand the complex series of financial transactions that affect costs. As rebates and price concessions throughout the supply chain are not visible to consumers, the process of setting UPLs by PDABs will be rigorous, transparent, and allow for public input in the rulemaking process.[110]

Consolidated drug purchasing models and opportunities

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

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[104] Center for Medicare & Medicaid Services; Federal Upper Limit; Affordable Care Act Federal Upper Limit. https://www.medicaid.gov/medicaid/prescription-drugs/federal-upper-limit/index.html Accessed November 22, 2022

[105] The Commonwealth Fund. "Allowing Medicare to Negotiate Drug Prices" May 5, 2021. https://www.commonwealthfund.org/publications/explainer/2021/may/allowing-medicare-negotiate-drug-prices. Accessed November 22, 2022

[106] Horvath Health Policy – Innovations in Health Care Financing. Why is a PDAB Important. November 2020 https://www.generalservices.state.nm.us/wp-content/uploads/2021/02/Why-is-a-Prescription-Drug-Affordability-Board-PDAB-Important-Nov-2020.pdf. Accessed November 22, 2022

[107] Ibid (Horvath)

[108] Presentation by Andrew York, PharmD, JD. Executive Director of the Maryland PDAB to the Oregon PDAB. October 19, 2022. https://dfr.oregon.gov/pdab/Documents/20221019-PDAB-document-package.pdf Accessed November 22, 2022

[109] Lila Cummings, Colorado PDAB Director. Presentation to the Oregon PDAB. October 19, 2022 https://dfr.oregon.gov/pdab/Documents/20221019-PDAB-document-package.pdf. Accessed November 22, 2022

[110] Colorado Senate Bill 21-175 Signed into law by Governor Jared Polis, June 16, 2021. https://leg.colorado.gov/sites/default/files/2021a_175_signed.pdf Accessed November 22, 2022

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. 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 before 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.

Here are examples of each model:

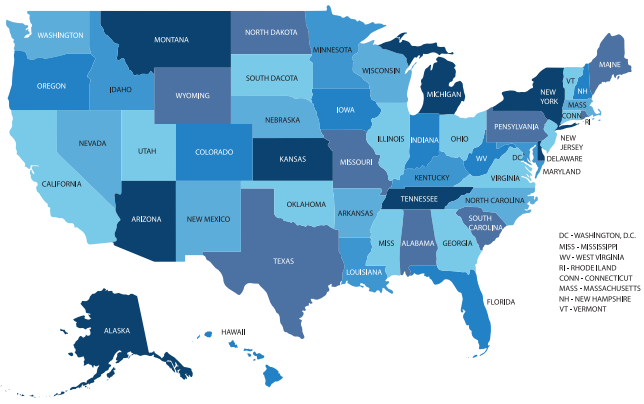
Intrastate models:

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 PBM 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.

   - 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.

   - Massachusetts established the State Office of Pharmacy Services (SOPS) in 1992, which standardized and consolidated multiple pharmacy care entities to improve cost-effectiveness, while retaining state oversight, control, and accountability.[111] SOPS administers



[111] Health Care For All-Massachusetts and the Greater Boston Interfaith Organization-FAQ: Establishing an Upper Payment Limit for Prescription Drugs: An Act to ensure prescription drug costs transparency and affordability (H. 1133/S. 706) April 3, 2019. Accessed November 22, 2022

the pharmacy services for almost 50 state facilities for 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 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 scope 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 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, the Top Dollar Program, 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 because 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 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 nonprofit 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 fees for 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 the Northwest Prescription Drug Consortium, now known as 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 PBM

programs, workers' compensation insurance pharmacy administration services, prescription drug voucher services, 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 CCO, local hospital, and union groups. Most recently, the state of Nevada joined ArrayRx and will implement ArrayRx services for state programs. ArrayRx is uniquely open to private sector employer health plans and union groups and offers discount cards for state residents.

Beyond interstate 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, 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.

Reverse auctions for PBM services

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. Reverse auctions are 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 by putting 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 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 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 that may not be not passed to states. Reverse auctions may create concessions from PBMs to pass along a greater share of monies received from manufacturers, but opponents 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), ArrayRx, and its current business model.

Conclusion and recommendations

PDAB studied the distribution and payment system of prescription drugs in Oregon and considered the complexity of how drugs move through the supply chain. The prescription drug market is a complex system, with many players serving different functions. While all are committed to improving health outcomes, each may have competing or different priorities.

Medicare, Medicaid, and commercial health insurance work hard to provide appropriate medication coverage to their enrolled members. However, each payor has its own processes and payment system structures for providing patient care. With so many complex core components -manufacturing, distribution, health system payment structures, and patient access - some aspects of the supply chain are outside the scope of this analysis. More research needs to be conducted to explore options to help public and private purchasers lower prescription medication costs.

The following proposed recommendations are to assist the Oregon Legislature in developing legislative changes to lower the cost and make prescription medications affordable in the state.

Recommendation 1: Implement (UPL)

As a concept, a UPL 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.[112] Maryland's PDAB has authority to implement upper payment limits for state and local government purchasers.[113] The Oregon Legislature proposed UPLs in the original language of PDAB's governing statute, Senate Bill 844, which allowed the board to establish upper limits to all prescription drug sales and reimbursement claims in the state of Oregon. The language was removed under Senate amendments. The Oregon PDAB 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 establish an UPL for drugs for state and local government purchasers.

[112] Senate Bill 21-175. Colorado Legislature (2021). https://leg.colorado.gov/sites/default/files/2021a_175_signed.pdf. Accessed Nov. 22, 2022.

[113] Chapter 692 of 2019, 21-2C-13. Maryland. https://mgaleg.maryland.gov/2022RS/Statute_Web/ghg/21-2C-13.pdf. Accessed Nov. 22, 2022.

Recommendation 2: 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 PBMs, and GPOs, which are either used or owned by PBMs to operate rebate programs, to report information to the Drug Price Transparency (DPT) program at Oregon Department of Consumer and Business Services (DCBS). Specifically, PDAB recommends that the DPT program be given statutory authority to collect the following information from PBMs and GPOs operating under this model annually:

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

PDAB recommends 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 or GPO. 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.

Recommendation 3: DPT Program to expand reporting requirements for patient assistance programs (PAP)

While various aspects of PAP have been discussed in recent legislative sessions, no bills have passed to address their use from either a transparency perspective or their interaction with co-pay accumulators and their effects on the cost to consumers or for the health care system. 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 health care 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", – which is an 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 PAP reporting requirements are poorly matched to the market landscape. Currently, only drugs subject to price increase reporting requirements must also report PAP information. New-to-market drug reports do not require any PAP reporting, and most price increase reports are for generic drugs, which are extremely unlikely to maintain a PAP.

PDAB recommends removing the PAP reporting requirement from DPT price increase reports and requiring all manufacturers to report annually on all patient assistance programs they maintain or fund. This collection of more comprehensive data on PAP 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.

Recommendation 4: Expand reporting to more insurers for the DPT Program

Currently, 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 plans (Those 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 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.

Recommendation 5: 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 advocacy 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. PDAB recommends that patient advocacy groups disclose their industry funding sources publicly for contribution amounts received from Third parties, including manufacturers, PBMs, or other groups, and what percentage of gross in income of the organization during the immediately preceding calendar year is attributable to payments, donations, subsidies, or other contributions from each manufacturer, third party, PBM, or group.

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 percent AMP.

GPO: Group Purchasing Organizations. These entities represent groups of drug purchasers, such as hospitals and health systems. A GPO negotiates with manufacturers on behalf of its clients for either up-front, oninvoice discounts or back-end rebates. Importantly, GPOs do not take ownership of a drug; they are not part of the supply chain. GPOs essentially negotiate a purchase-order from which members of the buying group can purchase in whatever quantities needed. Wholesalers supplying to GPO members typically provide the drug at the discounted price on the invoice and then receive a rebate from the manufacturer of the drug after the fact. GPOs may provide additional client administrative services as well.

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

Prescription Drug Affordability Board

2023 Roadmap

PDAB ROADMAP for 2023

Rules
- Rulemaking for Fee Structure
- Rulemaking for Affordability Criteria
- Schedule Rulemaking Advisory Committee (RAC) meetings

Annual Reports
- Generic Drug

Rules
- Implement Fee Structure
- Implement Affordability Criteria

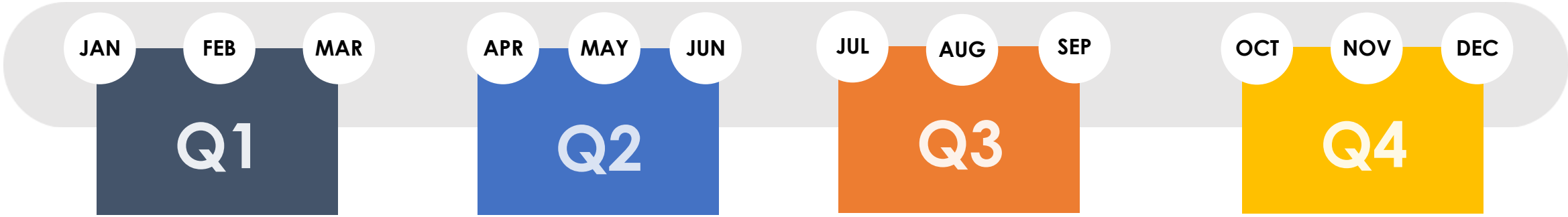
Studies
- Price trends for list of Rx
- Affordability of Rx
- Recommendations from Rx list

Report from DPT

Rx list of Carriers

Identify 9 Rx & Insulin
- Review list for 2024 review

Annual Reports
- Price trends for list of Rx
- Report of Affordability Reviews conducted by the Board
- Recommendations from Rx list



Oregon Prescription Drug Affordability Board

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2023 Board Meetings and Topics

TOPICS	Jan. 18 PDAB Meeting	Feb. 15 PDAB Meeting	March 15 PDAB Meeting	April 19 PDAB Meeting	May 17 PDAB Meeting	June 21 PDAB Meeting	Report Due Date
Work Plan	**Board approval**						
Affordability rulemaking	**Rule development**					**Approval of rule**	
Fee structure rulemaking	**Rule development**					**Approval of rule**	
				RAC meetings and hearing			
Generic Drug Report*	**Presentation of outline to board**		**Presentation of report draft to board**		**Presentation of report draft edits to board**	**Board approval of final draft**	**06/01/23**

*Annually by June 1, the board conducts a study of the operation of the US market for generic drugs, both drugs dispensed by pharmacists and drugs administered by physicians, including:

1. The prices of generic drugs on a year-to-year basis
2. The degree to which generic drug prices affect insurance premiums
3. Annual changes in health insurance cost-sharing for generic drugs
4. The potential for and history of generic drug shortages
5. The degree to which generic drug prices affect annual spending in the state medical assistance program
6. Any other topic the board considers relevant to the cost of generic drugs

2023 Board Meetings and Topics

TOPICS	July 19 PDAB Meeting	Aug. 23 PDAB Meeting	Sept. 20 PDAB Meeting	Oct. 18 PDAB Meeting	Nov. 15 PDAB Meeting	Dec. 13 PDAB Meeting	Report Due Date
Identify list of drugs & insulin	**Identify list of drugs & insulin**						
SB 844, Section 5 Report and Recommendations (1, 2 & 3)			**Presentation of outline to board**	**Presentation of report draft to board**	**Presentation of report draft edits to board**	**Board approval of final draft**	**12/31/23**

(1) Price trends for the list of prescription drugs provided to the board by the DCBS

(2) The prescription drugs that were reviewed under section 2 of SB 844

(3) Recommendations, if any, for legislative changes necessary to make prescription drug products more affordable in Oregon.