

Oregon Prescription Drug Affordability Board

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Agenda

Date: June 21, 2023 | Time: 9:30 a.m. This agenda is subject to change.

Meeting name	Prescription Drug Affordability Board	Board Members: Chair Akil Patterson; Vice Chair Shelley Bailey; Dr. Daniel Hartung; Dr.	
Meeting location	Virtual	Richard Bruno; Amy Burns, Robert Judge (A);	
Zoom link	Register for the meeting	Dr. Rebecca Spain (A), John Murray (A) *(A) denotes Alternate Member Staff: Ralph Magrish, executive director; Cortnee Whitlock, policy analyst; Stephen Kooyman, project manager; Amanda Claycomb, research analyst; Brekke Berg, data analyst; Melissa Stiles, administrative	
		specialist; Jake Gill, counsel	

Subject		Presenter	Time Allotted
	Call to order, roll call, and <u>approval of minutes</u>	Chair Patterson	5 minutes
	Executive director's program update	Ralph Magrish	10 minutes
	Overview of Medicare negotiations	Jane Horvath, consultant, Horvath Health Policy	10 minutes
	Presentation by <u>T1International</u> * Questions from board members	Allison Hardt, advocacy manager	25 minutes
	Legislative bills and session discussion	Jesse O'Brien, policy manager	10 minutes
	Board Review * Data call template for carriers	Ralph Magrish	20 minutes
	Announcements	Staff	5 minutes
	Public comment	Chair Patterson	10 minutes
	Adjournment	Chair Patterson	2 minutes

Next meeting

July 19, 2023, at 9:30 a.m.

Accessibility

Anyone needing assistance due to a disability can contact Melissa Stiles at least 48 hours ahead of the meeting at pdab@dcbs.oregon.gov or 971-374-3724.

How to submit public comment

Oral testimony

For oral comments, please submit the PDAB public comment form no later than 24 hours before the PDAB meeting. The form is located on the Oregon Prescription Drug Affordability Board website here: https://dfr.oregon.gov/pdab/Pages/public-comment.aspx

Written testimony

For written comments, please submit the PDAB public comment form no later than 72 hours before the PDAB meeting. The form is located on the Oregon Prescription Drug Affordability Board website here: https://dfr.oregon.gov/pdab/Pages/public-comment.aspx Written comments will be posted to the PDAB website.

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 (PDAB) Meeting Wednesday, May 17, 2023 Draft Minutes

Chair Akil Patterson called the meeting to order at 9:32 am and asked for the roll call.

Board members present: Chair Akil Patterson, Vice Chair Shelley Bailey, Dr. Amy Burns, John Murray (alternate), Dr. Rebecca Spain (alternate)

Board members absent: Dr. Richard Bruno, Dr. Daniel Hartung, Robert Judge (alternate), all excused

Chair Patterson appointed alternates John Murray and Rebecca Spain to vote in today's meeting due to board member absences.

Approval of the minutes: Chair Akil Patterson asked if board members had any changes to the April 19, 2023, minutes on Pages 3-5 in the agenda packet: https://dfr.oregon.gov/pdab/Documents/20230517-PDAB-document-package.pdf and there were none. Vice Chair Shelley Bailey moved to approve the minutes and John Murray provided a second.

MOTION by Shelley Bailey to approve the April 19, 2023 minutes. Board Voice Vote:

Yea: Amy Burns, John Murray, Rebecca Spain, Shelley Bailey, Akil Patterson

Nay: None.

Motion passed.

Program update: Executive Director Ralph Magrish introduced Brekke Berg, PDAB's new policy analyst. Staff will soon award a contract to Harvard's Program on Regulation Therapeutics and Law (PORTAL), the group that presented to the board in February. In June, T1International will present to the board about diabetes. In July, the OHA's Oregon Cost Growth Target program director will speak to the board about their annual report, which is relevant to the board's upcoming work with affordability reviews. Staff may pause scheduling of presentations when the board begins working on affordability reviews and the 2023 report for the Legislature. The board may schedule an informational meeting in between board meetings. An agenda item was added today: Jesse O'Brien, policy manager with the Division of Financial Regulation, will provide a legislative update.

John Murray said he needed to let Chair Patterson know, under advisement of the Oregon Ethics Commission, he must declare a potential conflict of interest as the owner of Murray Drugs. Inc., comprised of three independent pharmacies in Eastern Oregon. They have pharmacy services contracts with PBM and insurance companies in Oregon. He said the ethics commission determined there could be a potential conflict of interest when PDAB discusses specific drugs or related matters. **Chair Patterson** thanked John Murray and said he and Ralph Magrish would have a meeting with counsel to discuss the declaration.

Legislative Update: Jesse O'Brien, policy manager for the Division of Financial Regulation, reviewed the document on <u>Pages 7-8</u> of the agenda packet for the board.

Sean Dickson, senior vice president of pharmaceutical policy and strategy, America's Health Insurance Plans (AHIP), presented on the insurance carrier perspective of high drug costs (<u>Pages 9-22</u> in the agenda document). He provided recommendations shown on <u>Page 20</u>: accelerate the availability of biosimilars; reform the system

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for provider-acquired drugs; and address drug manufacturers' abuse of charitable structures. He discussed federal solutions for prescription drug affordability on Page 21.

Amy Burns said the cycle for rebates and rebate collection can be as much as two years, whereas, plan years are 12 months. Generated rebates will not come back into health insurance coffers until the next year, which is a whole new plan year. If that savings is passed on to everyone and people move in and out of plans, how do those savings compare to savings at the point of sale? **Sean Dickson** said his understanding is that rebates are happening more frequently. The important part is the net price after rebates is being factored into the overall actuarial value of the structure of the plan design.

John Murray asked about the recommendation to limit use to specialty pharmacies. His concern is that specialty pharmacies are more expensive. Sean Dickson said he was talking about physician-administered drugs and having the drugs delivered to the hospital by the specialty pharmacy. This will help avoid the hospital mark ups on the drugs, which can be as high as 120 percent. By comparison, physician-owned offices are marking up drugs 8-10 percent. Rebecca Spain asked if the markup was on the drugs only, not on the infusion costs. Sean Dickson said he is referring to the ingredient cost of the drug from the specialty pharmacy compared to the amount the hospital bills for that same product if they bought it themselves. He said hospitals charge commercial insurance higher amounts than what they charge Medicare and Medicaid. Shelley Bailey said, as far as drug costs, the board will be looking at the wholesale acquisition cost (WAC) in its reports. She asked about an ASP + plus crosswalk to the WAC minus to help the board evaluate drugs that are outpatient administered. Sean Dickson said they use data from a commercial claim data base. They look at paid amounts within commercial markets, what plans reimburse specialty pharmacies for this drug ingredient, compared to what they reimburse hospitals and independent provider offices. There is a study comparing this data to ASP + located here: https://www.ahip.org/resources/markups-for-drugs-cost-patients-thousands-of-dollars. Amy Burns asked if the context was provider-administered drugs only, such as infusions, and he confirmed yes.

Akil Patterson asked how pay-for-delay policies are moving along. Sean Dickson said the pay-for-delay bill was not included in the recent package that went through the Senate Health Committee. He said one challenge of taking on the pay-for-delay practice is manufacturers have found ways to achieve the same deals without using the historical structure. There have been proposals to allow the Federal Trade Commission to have more authority over those. In addition, AHIP is focused on reducing the barriers to the Federal Drug Administration (FDA) approval for generics and biosimilars. These barriers encourage the use of pay-for-delay deals. One of the reasons the generic manufacturer will engage in this process is because of the high litigation cost for getting the drug approved and patents dismissed. He said it is important to address the underlying incentives for why those strategies are being used.

Affordability review rule and approval: Cortnee Whitlock discussed the timeline for approval of the affordability review rule on Page 23 of the agenda packet. She reviewed the Statement of Need and Fiscal Impact on Pages 23-28, and recent updates to the affordability review rule on Pages 29-46. Staff added a definition for therapeutic alternative and asked board members for feedback. Amy Burns said the definition works and is similar to Medicare's. Rebecca Spain agreed from a clinical standpoint. John Murray agreed and said this will allow the board to find less expensive options. Shelley Bailey recommended a data source, Myers and Stauffer's fee-for-service, Medicaid pricing for acquisition cost, for f) analysis to consider acquisition cost for pharmacies as shown on Page 40. She hopes the board will take into consideration net price through the 340B program in the affordability review rule. Ralph Magrish said the board has no statutory authority to find 340B pricing. Cortnee Whitlock explained that is the reason she moved it from the data section to the stakeholder

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feedback section of the rule. Vice Chair Shelley Bailey asked about including the word "net drug prices." Ralph Magrish and Cortnee Whitlock said the legislation narrows the board scope and counsel recommended not using "net."

Chair Akil Patterson called for a motion to approve the affordability review rule as presented. **Amy Burns** made the motion and **Rebecca Spain** provided the second.

MOTION by Amy Burns to approve the affordability review rule as presented. Board Vote:

Yea: Amy Burns, John Murray, Rebecca Spain, Shelley Bailey, Akil Patterson

Nay: None. **Motion passed**.

Final Generic Drug Report: Cortnee Whitlock reviewed the final version of the generic drug report on Pages 47-60. Once the board approves the report, staff will send it to Oregon Legislature, as directed in Senate Bill 844 (2021). She asked if board members had comments and there were none. Chair Akil Patterson called for a motion to approve the generic drug report as presented. John Murray made the motion and Shelley Bailey provided the second.

MOTION by John Murray to approve generic drug report.

Board Vote:

Yea: Amy Burns, John Murray, Rebecca Spain, Shelley Bailey, Akil Patterson

Nay: None.

Motion passed.

Public comment: The chair allocated three minutes for public comment. Dharia McGrew, state policy director, PhRMA, provided testimony to the board. PhRMA's written comments are posted online: https://dfr.oregon.gov/pdab/Documents/20230517-PDAB-public-comment.pdf.

Adjournment: The meeting was adjourned at 11:04 a.m. by **Chair Akil Patterson**, with a motion by **John Murray** and a second by **Amy Burns**.

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Things to Think About Medicare Maximum Fair Price Jane Horvath

Medicare Negotiation – key points

- Focus on drugs in monopoly position.
 - Some drugs will be on patent via multiple patent applications
- Some exemptions from negotiation (list not exhaustive)
 - Drugs with market competition
 - Drugs approved for one indication and that indication is a rare disease
 - A drug that is a small portion of total Medicare spend and is the preponderant source of revenue for a company (the small biotech exemption). Lasts only 3 years.
- Use existing net market prices as a key part of ceiling price
 - Drugs in monopoly position don't need to provide deep price concessions
 - Net and market price may look similar
- Negotiated price will be PUBLIC for other health plans and purchasers to see
 - It is included in Medicaid best price math so Medicaid may get a benefit
- Medicare price will not travel through the supply chain but will be at the point of service
 - Operationalized by rebates

Medicare Negotiations – possible short term effects

- Average launch price could grow fairly quickly because
 - MFP ceiling price is based on market prices
 - Medicare law and Medicaid law now have substantial rebate penalties for price increases in excess of CPI growth
 - Negotiation will involve comparing price to prices of therapeutic competitors
- Innnovator life cycle management will change
 - Drug makers have spent decades on new ways to limit competition
 - Now manufacturers need to assure competition to be exempt from negotiation
 - Manufacturers have control of their patent rights and data exclusivities...
 - Manufacturers can share protected data with chosen competitor
 - Manufacturer maintains price and competitor launches at price higher than if innovator and both are exempt from negotiation
 - This is good except for the unknown effect of higher launch prices (if they occur)
- Will industry patent strategy change?
- Will the orphan drug designation gold rush slow down?

Other RX Market Disruptions – Pressure on Rx Price and Business Models

- All 3 leading insulin companies dramatically lowering the price of long acting insulins and managing distribution.
- One Humira biosim announced a stunning low price for a July launch
 - \$995/2 vial pack v \$7000/2 vial pak (per month)
 - Likely to shake up pricing of all other Humira biosim list pricing
- CIVICA Rx, CIVICA Script, state manufacturing
 - Focus on off-patent, non exclusivity products
 - Developing their own supply chains and distribution channels including bricks & mortar
- Low Cost Drugs
 - Began 2yrs ago as an on-line, cash only, generic pharmacy with a flat 15% mark up.
 - In 2023, added *patented* Invokana (diabetes) and branded Humira biosim products at reduced prices
 - Also developing distribution and retail sales locations
- Brands bringing products to market with two list prices
- Employers creating new PBMs for greater control, flexibility to work with market disrupters (Low Cost Rx), and better market behavior

First Medicare Negotiation Lawsuit by Merck

- Violates the First Amendment rights to free speech
 - the negotiation process is compelled or face "crippling" financial penalties
 - accept the negotiation as "fair" whether Merck views the process as fair
- Violates the Fifth Amendment right to fair compensation if govt takes private property for public use
 - Complaint states that negotiated fair price will not reflect fair market value
 - Complaint does not suggest that "fair market value" of sole source drugs 9+ years on the market results from controversial use of the US patent system and orphan drug designation program to fend off competition for years on end.
- Suggests that Medicare law should have simply set a payment limit on Medicare drugs so that:
 - Pharmaceutical companies could refuse the payment limit and boycott sales to Medicare
 - Causing 'enormous' political backlash by the public against Medicare when drugs become unavailable for Medicare beneficiaries Page 4 #7 of the complaint.
- Filed June 6 2023

Thank You

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OR PDAB

June 21, 2023







Vision

We believe in a world where everyone with type 1 diabetes – no matter where they live – has everything they need to survive and achieve their dreams.

Mission

We support local communities by giving them the tools they need to stand up for their rights so that access to insulin and diabetes supplies becomes a reality for all.



#insulin4all Movement



#insulin4all is a global movement of people with diabetes and allies fighting for affordable and accessible insulin, supported by T1International

The #insulin4all campaign was launched in 2014 in the lead up to World Diabetes Day by T1International – it was originally a campaign to draw attention to diabetes issues worldwide



About Type 1 Diabetes



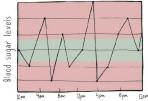




Insulin is the key that allows the body to use sugar (carbohydrate) as energy.



Constant monitoring of blood sugar levels and carbohydrate intake is part of life with Type 1 diabetes.



Managing diabetes is a complicated task even with the best tools and technology.



Some people still cannot access their essential insulin or diabetes supplies.







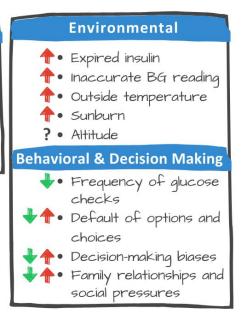


Factors that Impact Blood Glucose

Food ↑ ↑ Carbohydrate quantity → ↑ Carbohydrate type Protein • Caffeine Alcohol ♣ ♠ • Meal timina Dehydration ? · Personal microbiome Medication Medication dose Medication timing Medication interaction Steroid administration Niacin (Vitamin B3)

Biological 1 Insufficient Sleep Stress and illness · Recent hypoglycemia 👚 • During-sleep blood sugars Dawn phenomenon Infusion set issues · Scar tissue and lipodystrophy ▶ Intramuscular insulin delivery Allergies A higher glucose level Periods (menstruation) 1 Puberty · Celiac disease ♠ Smoking

Activity Light exercise ♦ ↑ ♦ High-intensity and moderate exercise → ↑• Level of fitness/training Time of day ◆↑ Food and insulin timing





T1D Treatment

- Management Insulin!
 - Injections, Pens, Pumps, Inhaled Insulin
 - Test strips and CGMs
 - Ketone testing
 - Glucagon injection
- Analogue vs. human insulin
- Authorized Generics & Patient Assistance Programs



The Problem

Diabetes in Numbers

- Approximately 463 million adults (20-79 years) living with diabetes (both type 1 and type 2).
- By 2045, estimates are that the number of people with diabetes will be 700 million.
- 79% of adults with diabetes live in low- and middle-income countries.
- Diabetes causes approximately 4.2 million deaths annually.
- Diabetes accounts for 10% of total health expenditure.
- More than 1.1 million children and adolescents are living with type 1 diabetes.
- Other than for children, separate global estimates of diabetes prevalence for type 1 and type 2 do not exist. This lack of data around type 1 diabetes is a big problem.
- Some say **10**% of people with diabetes have type 1, so an **estimated 40-45** million people worldwide live with type 1 diabetes.



The American Insulin Crisis

- Since the 1990s, the cost of insulin has increased <u>over 1,200%</u>, yet the cost of production for a vial of most analog insulin formulas is <u>between \$3.69 and \$6.16</u>.
- Between 2001 and 2015 the price of Humalog insulin <u>increased 585%</u>. Spending by patients with type 1 diabetes on insulin nearly doubled from 2012 to 2016 alone, increasing from \$2,900 to \$5,700.
- List prices of insulin have been rising at the <u>same rate at the same time</u> for 10 years.
- Many Americans are on the hook for the full list price for insulin 8.8% of Americans are uninsured and 47% have high deductible plans.

Insulin is as necessary as water to a person with type 1 diabetes



1 in 2 worldwide cannot access or afford insulin











We Need #insulin4all Urgently

1 in 4* people living with diabetes in the United States has had to ration insulin due to cost.

For people with type 1 diabetes, like Alec Smith, and many others on our In Memory page, rationing is fatal, causing death in days or even hours.







Solutions

Campaigning: US Federal Advocacy

- Insulin price caps policy
 - A \$35 co-pay cap was put into effect in the IRA for Medicare recipients
 - Capping the price of insulin at the pharmacy counter for anyone who needs it, regardless of insurance, will save lives as we work on more structural changes for free insulin and all supplies for everyone who needs it.
- Patent policy and regulation
 - Current patent rules allow companies to create patent thickets around products and discourage competition

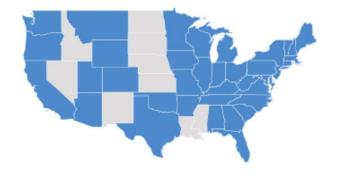


Campaigning: US State Advocacy

Our 41 - and growing-#insulin4all Chapters, have achieved state-based legislative wins

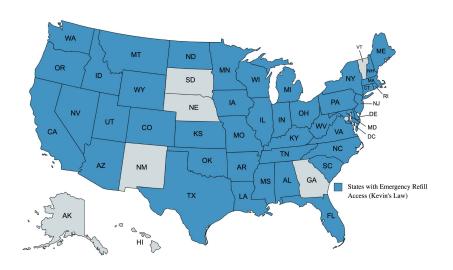




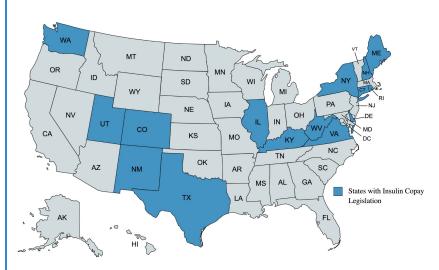




States with Emergency Refill Access(Kevin's Law)



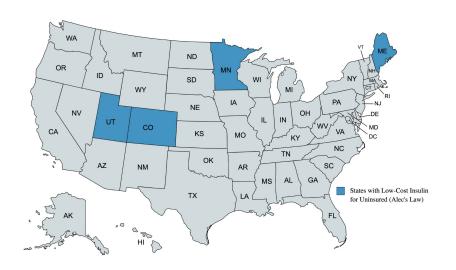
States with Insulin Copay Legislation



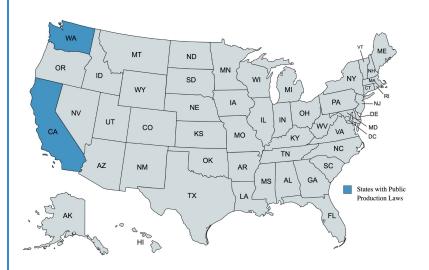
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States with Low-Cost Insulin for Uninsured(Alec's Law)



States with Public Production Laws



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Oregon Related Policies and Programs

- Co-pay cap HB 2623: \$75 per prescription or 90-day supply at \$250
 - Supplies are not covered and there are no provisions for the uninsured
- Kevin's Law <u>SB9</u> (2019) can prescribe the smallest available package up to 3x per year, no insurance mandate
- Array Rx discount card program



Expanding Pharmacist Scope of Practice

- Pharmacist scope of practice refers to the boundaries within which a
 pharmacist may practice, usually as it relates to drug dispensing and
 prescribing medication. Some states allow for patient or
 population-specific expansion (most restrictive) and others allow
 statewide expansion (less restrictive) of pharmacist scope of practice.
 - Statewide standing orders: An order is signed by a single physician on a state public health order and can be carried out by a pharmacist when predetermined conditions are met (e.g., contraceptives in California, Oregon, Colorado, New Mexico, Hawaii, and Maryland; Naloxone in many states).



Insulin Lispro Survey

- In March 2023, Eli Lilly, Novo Nordisk, and Sanofi lowered the list price of some of their insulins.
 - Eli Lilly lowered their insulin Lispro to \$25, and CEO David Ricks testified in front of Congress on May 10 that it would be available for \$25.
 - This is so far not the case for patients across the US.

Public Pharma

- The number of people with type 1 and type 2 diabetes is increasing; states making this investment are showing a commitment to their citizens for the future.
- States who invest in public manufacturing of insulin and other medicines are also creating jobs and taking ownership of the supply chain.
- Public actors in the United States have a long history of producing pharmaceuticals.
- This crisis affects everyone, not only low income or uninsured people.
- Members of the federal government are pursuing public manufacturing as a matter of national security, states can do the same.



Any solutions that we pursue must actually make it to patients. Medicines being affordable does not help if patients cannot access them.







Data call draft template for insurance carriers

Ralph Magrish, executive director
Oregon Prescription Drug Affordability Board
& Drug Price Transparency Program

Stephen Kooyman, project manager Prescription Drug Affordability Board

Data call draft template for insurance carriers

The purpose is To collect information from insurance companies not captured in the annual insurer submissions to the Drug Price Transparency program.

This is a draft with placeholders and subject to change. It is similar to data call templates used by DCBS staff.

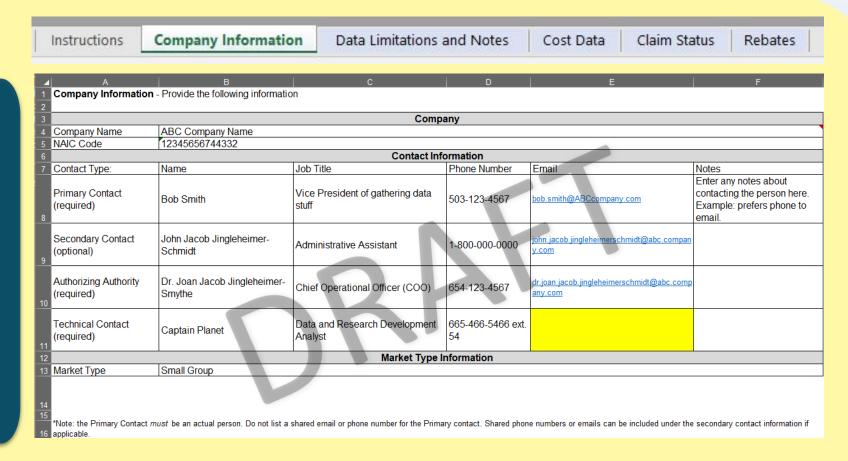
Data Limitations and Notes Instructions Company Information Cost Data Claim Status Rebates **Oregon Prescription Drug Affordability Board** Department of Consumer and Business Services Oregon Prescription Drug Affordability Board (PDAB) Data call for Health Insurance Companies in Oregon Instructions for completing this report. Due Date: MMMM DD, YYYY The purpose of this Excel sheet is for health insurance plans to report on required data on prescription drugs under both pharmacy and medical benefits for policies or certificates issued in Oregon during 2022. Health insurance plans should fill out the information on each of the tabs listed below. The tabs to complete are colored light blue.





Data to collect: company information

Insurance companies would list their contact information on this tab.







Data limitations and notes

Insurers should use this tab to list any data limitations, quality concerns, or other notes about how the data was collected.

They should list a specific section or data point, or note a data limitation that applies to multiple values or even the entire template.

	A CONTRACTOR OF A CONTRACTOR O			
Data Limitations and Notes	Cost Data Claim Status Rebates			
l B	C			
Code: 12345656744332				
larket: Small Group				
5 Click here to enter or correct Company Information				
▼ Data Point	▼ Data Quality to Limitation Notes			
	Cost data for drug [name] has [data			
Other (See Notes)	limitation].			
	Data excludes [item] which applies to [list of			
	impacted numbers].			
	Company Information: Ipany: ABC Company Name Code: 12345656744332 Iarket: Small Group ation			

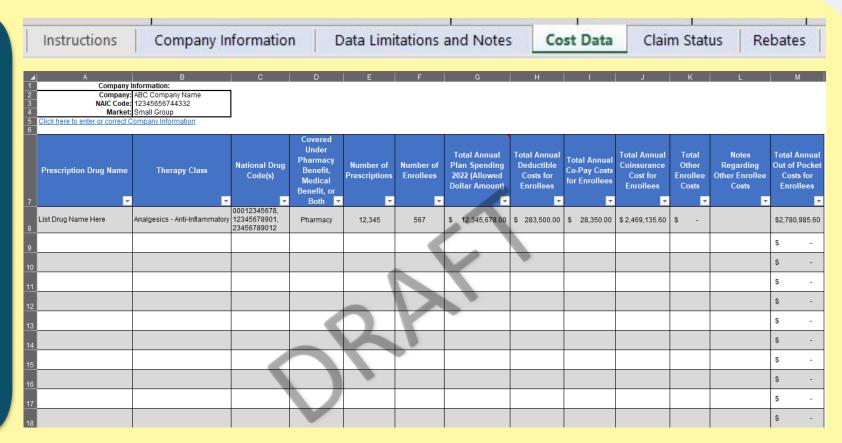




Data to collect: cost data

This tab captures information about costs to enrollees, including copays, coinsurance, and deductibles.

For each drug the PDAB team is reviewing, the insurance company should list the associated NDCs from their billing information, number of prescriptions, enrollees, and associated costs to the enrollees.



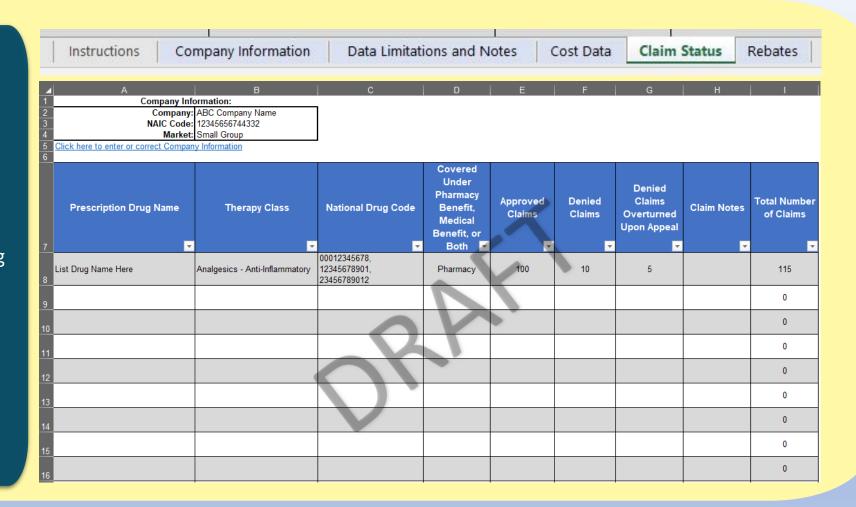




Data to collect: claim status

Insurance companies should list the number of approved and denied claims for each drug the PDAB team is reviewing.

This data will help the PDAB team check for any potential trends regarding the rate at which claims are denied for particular drugs, an indicator of potential patient access issues. For example, do certain high-cost drugs have a higher rate of denied claims?

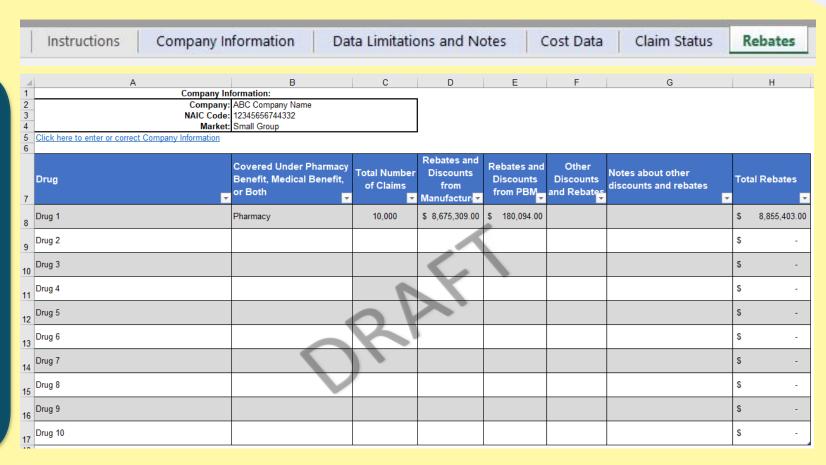






Data to collect: rebates

PDAB is still determining how to best calculate average monetary price concessions, discounts and rebates expressed as a percentage of the price for the prescription drug under review.







Data to collect: therapeutic alternatives

Tasked with collecting information on:

- The estimated price for therapeutic alternatives to the drug that are sold in this state;
- The estimated average price concession, discount or rebate the manufacturer provides or is expected to provide to health insurance plans and pharmacy benefit managers in this state for therapeutic alternatives;
- The estimated costs to health insurance plans, based on patient use of the drug consistent with the labeling approved by the United States Food and Drug Administration and recognized standard medical practice.





Insurer data call and affordability review timeline

DRAFT

- Finalize template draft design and share with board: June 21
- Carrier socialization begins June 23
- Board approves template and timeline: July 19
- Data call template distributed to carriers July 20 and returned to PDAB team by August 31
- PDAB data review, clean up and processing begins September 1
- Study Rx data to determine drugs to select for review: August 23, September 20
- Identify top 9 selected drugs and an insulin product and conduct affordability reviews: October 18, November 15
- Board approval of report price trends and list of nine drugs and an insulin product:
 December 13





Board roadmap: setting the course for 2023

JUNE JULY **AUGUST SEPTEMBER OCTOBER** NOVEMBER **DECEMBER** Study top 9 Approval of Affordability Affordability Study Rx • Study top 9 Annual rule takes selected selected rule hearing review of data to report. June 22. drugs and board effect August determine drugs and · Report due to policies. 1st. insulin insulin drugs to the Oregon product for product for select for Review 2Q Legislature Study Rx data affordability affordability review. data. to determine December 31. concerns. concerns. drugs to select for review.



