Oregon Prescription Drug Affordability Board

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Agenda

Date: **February 15, 2023** | *Time*: **9:30 a.m.**
This agenda is subject to change.

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; Jacob Gill, counsel; Pramela Reddi, counsel

Subject	Presenter	Time Allotted
☐ Call to order, roll call, and approval of minutes	Chair Patterson	5 minutes
☐ Presentation by: PORTAL BWH Harvard Questions from board members	Aaron Kesselheim MD, JD, MPH, Adam Raymakers, PhD, and Ben Rome MD, MPH	60 minutes
☐ Executive director's program update	Ralph Magrish	4 minutes
☐ Board discussion: Draft generic drug report outline	Cortnee Whitlock	5 minutes
☐ Board discussion: Fee structure rule development	Ralph Magrish, Cortnee Whitlock	5 minutes
☐ Board discussion: Affordability review rule development	Cortnee Whitlock	25 minutes
☐ Announcements	Staff	3 minutes
☐ Public comment	Chair Patterson	10 minutes
☐ Adjournment	Chair Patterson	2 minutes

Next meeting

March 15, 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. advance.

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

Oregon Prescription Drug Affordability Board Meeting
Wednesday, January 18, 2023
Draft Minutes

Chair Akil Patterson called the meeting to order at 9:34 am and asked for the roll call.

Board Members present: Chair Akil Patterson (left at 11 am), Vice Chair Shelley Bailey, Dr. Richard Bruno (arrived at 10:35 am), Dr. Amy Burns (left at 11 am), Dr. Daniel Hartung (left at 10:30 am), John Murray (alternate), Dr. Rebecca Spain (alternate)
Board members absent: Robert Judge (alternate)
The chair appointed Dr. Rebecca Spain and John Murray, alternates, to vote in today's meeting, if necessary.

Approval of the minutes: Chair Akil Patterson asked if board members had any changes to the Dec. 14, 2022, minutes on Pages 3-6 in the agenda packet: https://dfr.oregon.gov/pdab/Documents/20230118-PDAB-document-package.pdf. Amy Burns asked for a correction on Page 2 to read: "Amy Burns suggested using "pharmacy claim" instead of "encounter" in other parts of the report." **Daniel Hartung** moved to approve minutes with the correction and **Vice Chair Shelley Bailey** provided a second.

MOTION by Daniel Hartung to approve the Dec. 14, 2022, minutes with the correction.
Board Voice Vote:
Yea: Amy Burns, Daniel Hartung, Shelley Bailey, Akil Patterson, Rebecca Spain.
Nay: None.
Motion passed.

Program update: Executive Director Ralph Magrish said he has been invited to speak at the Oregon Health Authority's Cost Growth Target Advisory Committee at 10:30 am today. He will present the board's recommendations for their review, discussion and consideration for endorsement. Sen. Deb Patterson, chair of the Senate Health Care Committee, will be sponsoring and introducing a bill that includes all of the 2022 PDAB recommendations. The vacant research analyst position is now open for recruitment through January 26. The link to the recruitment is on the PDAB website. Please share in your networks. Next month's board presentation will be from PORTAL, the contractor working through NASHP to provide technical assistance to state PDABs. At last month's meeting, board members requested 14 presenters for 2023 meetings. Staff will put together a calendar for the board soon.

Brian Mayo, executive director, and Kevin Russell, central Oregon director, Oregon State Pharmacy Association (OSPA), gave a presentation from slides on Pages 7-24 in the agenda document. They gave a summary of the OSPA report, which is available online: https://oregonpharmacy.org/ When Bi-Mart pharmacy closed 18 months ago, OSPA hired 3-Axis Advisors to do a study. Eighty-six of Oregon's estimated 534 retail community pharmacies, 16.1 percent, participated. The study examined prescription claims and reimbursement data for three years (2019-2021), which accounted for 12 million claims. In 2018, the cost of a pharmacy to dispense a drug was $12.40, increasing to an estimated $15 in 2023. Yet pharmacies are actually getting paid only $7, they said. The OSPA report reached five conclusions, shown on Page 20 of the agenda packet. The OSPA recommends changing how people are paid with 11 recommendations shown on Pages 22-23. OSPA is supporting House Bill 3013, which requires pharmacy payments of no less than Oregon average actual acquisition cost plus a dispensing fee established by Oregon Health Authority.

Questions from the board: Vice Chair Shelley Bailey asked if specialty pharmacies are included in the average, actual acquisition cost, which is derived from a survey of retail and mail order pharmacies. She said specialty pharmacies are not included in the National Average Drug Acquisition Cost (NADAC). Kevin Russell said they will have to research the question. Vice Chair Shelley Bailey recommended having Myers and Stauffer present to the board, the company that conducts these surveys in Oregon and nationally.

Daniel Hartung said he reviewed the OSPA report and appreciated today's high-level summary. He said OSPA presented two contrasting slides, the break down by margin where pharmacies break even and where they push themselves in the black. The notion is all their margin is made in the top five percentile of prescriptions, which he presumes are high-expense drugs, basically getting paid more than what they are paying, in terms of the NADAC. He asked if this is a correct interpretation. Kevin Russell said there are varying examples. Daniel Hartung asked if dimethyl fumarate is an example, as shown on Page 18. Kevin Russell said yes but those amounts were not paid to pharmacies in the study. He assumes they were paid to a specialty pharmacy.

Rebecca Spain said the presentation shows the proposals would be beneficial to small and independent pharmacies but asked how will they be received by large pharmacies. Kevin Russell thinks it would help all pharmacies. The chain pharmacies are suffering just like everyone else, having problems with service and staffing, so they should equally benefit from the changes, he said.

Amy Burns said she also read the OSPA report. She asked if the reason OSPA focused on Medicaid is because that's what data was available. She said the study looked at 16 percent of the pharmacies in Oregon, a narrow sliver, and asked if they calculated a survey sample size. Kevin Russell said it was a significant sample size. Brian Mayo said the data is similar to other state findings and is a good sample size. **John Murray** said the OSPA information is very accurate. He thinks the Secretary of State audit will echo the OSPA survey results. He said the direct and indirect remuneration (DIR) fees went from $65,000 to $109,000 this year, which is unsustainable. The suggestions for changes to the system are very important, he said.

Vice Chair Shelley Bailey said she appreciates the call for transparency in prescription costs. There are companies doing this, such as Cost Plus Drug Company, mentioned in the PDAB report. Average actual acquisition cost is a published number. These transparent models are where things are heading in the future, she said. **Amy Burns** said the last suggestion on Page 23 looking at the California model is something already occurring in Oregon Medicaid, part of the 2020 changes in the CCO model.

Legislative bills and session discussion: Jessie O'Brien, policy manager, Division Financial Regulation, reviewed the prescription drug-related bills introduced to the Oregon Legislature so far this session. The list is on Page 25 of the agenda packet. The 2023 Oregon legislative session started January 17. Staff is combing through the thousands of bills introduced to see which ones will have an impact on the programs or issues at DCBS. **Chair Akil Patterson** asked if HB 2725 would limit fees at point of sale only. **Vice Chair Shelley Bailey** said post adjudication charge backs allow PBMs to charge a Medicare DIR up to 180 days later. It is a system to allow lower network rates but is not as transparent as lowering the rate on the front end, she said.

Regarding HB 3013, **Chair Akil Patterson** asked if PBMs are licensed in Oregon currently. Jesse O'Brien said it is a registration requirement and there are 30 PBMs registered with DCBS now. The chair asked Jesse O'Brien about providing an update later in the session and he agreed to.

Board approval of amended public comment policy: Cortnee Whitlock, board policy analyst, reviewed the amended policy on Pages 26-27 of the agenda packet. The board will post written comments submitted to the

board on the PDAB website beginning Jan. 1, 2023. Chair Patterson asked for a motion and a second. Vice Chair Shelley Bailey made a motion to approve the amended public comment policy, with a second by. John Murray.

MOTION by Shelley Bailey to approve public comment policy as amended.
Board Vote:
Yea: Amy Burns, Rebecca Spain, John Murray, Shelley Bailey, Akil Patterson.
Nay: None
Motion passed.

Board approval of 2023 work plan: Cortnee Whitlock reviewed the roadmap for board work in 2023 shown on Pages 28-31 of the agenda packet. Chair Patterson asked for a motion and a second. Amy Burns made a motion to approve the 2023 work plan, with a second by Vice Chair Shelley Bailey.

MOTION by Amy Burns to approve the 2023 work plan.
Board Vote:
Yea: Amy Burns, Rebecca Spain, John Murray, Shelley Bailey, Akil Patterson.
Nay: None
Motion passed.

Board discussion on rulemaking – fee structure and affordability reviews: Cortnee Whitlock presented concepts for the fee structure, for collecting gross revenues from manufacturers, shown on Pages 32-42 of the agenda packet. She also discussed the affordability review criteria on Pages 37-38.

Vice Chair Shelley Bailey thanked Cortnee for working on a solution that is in alignment with the statute but is realistic with what's achievable. She appreciated making the base fee an option to discuss. Gross revenue doesn't always correlate with profit, she said. Relying on gross receipts may have a disproportional, negative impact on manufacturers of some high cost drugs that have good outcomes in helping Oregonians.

Amy Burns asked if the list would be drugs new to market or drugs that have been on the market for some time. Cortnee Whitlock said the statute states drugs marketed in Oregon the previous year. **Vice Chair Shelley Bailey** asked if they can link the Drug Price Transparency (DPT) information to the All Payer All Claims (APAC) data to see what medical or other expenses those drugs help offset.

Regarding the criteria on Pages 37-38, **Amy Burns** asked about adding pharmacy deserts to the equity list because it impacts access to medication. **Chair Akil Patterson** said he wants to keep the issues separate. **Amy Burns** agreed about having two distinct issues, though sometimes they are an overlapping Venn diagram, she said. **Richard Bruno** said in terms of language, he prefers to use under resourced communities. Cost and access are two of the biggest drivers leading to health inequities, he said.

Rebecca Spain said it might be helpful to consider the denominator, whether the drug is for a specific disease such as cancer, in thinking about total cost. The board should think about the population the drug is targeted to. **Amy Burns** said part of the problem when drugs are prescribed, many are not filled due to insurance not approving it or other reasons. The denominator, if it includes all prescriptions, will be different than all the prescriptions filled for that drug. That's important because it shows where the medications are not getting to the patients, she said. **Vice Chair Shelley Bailey** agreed and asked if it could be pulled from APAC data. She said the criteria could look instead for adjudicated claims, medications prescribed versus what someone was actually able to receive. She said knowing the diagnosis code could be helpful. Chair Akil Patterson said an emergency came up and he needed to leave the meeting. He asked Vice Chair Shelley Bailey to run the meeting.

Rebecca Spain asked about rare diseases, where the cost of the drug is a million times over. Is the board looking at the highest cost to the state but not at the individual with a rare disease, she said. **Amy Burns** said the board can look at both. She doesn't think the board should ignore something that is very, very high cost but is an orphan drug and only impacts a small group of people. She thinks it's worth looking at the whole spectrum. **John Murray** agreed and said, even the price of that one, costly drug can vary dramatically depending on how and where it is filled. **Shelly Bailey** asked if the wording could be individuals rather than residents of Oregon because someone does not have to be a resident to qualify for assistance programs in Oregon. **Rebecca Spain** said she read the first criteria as taking each drug, looking at the major health plans, and seeing if it would be approved, or how difficult it would be to get that drug through major health plans in the state.

Vice Chair Shelley Bailey recommended sharing the PDAB meeting information with the medical community. If the board lets doctors know, the providers can tell patients about this information to encourage people to participate and share their stories. **Richard Bruno** said he and Dr. Rebecca Spain are members of professional organizations and could spread the word about opportunities to testify.

Announcements: Ralph Magrish, executive director, rejoined the PDAB board meeting and said the Cost Growth Target Advisory Committee meeting voted to endorse the Prescription Drug Affordability Board's recommendations. Stephen Kooyman, project manager, said staff would be providing tablets and state email addresses soon so all board correspondence and communication will take place through state devices.

Public comment: The vice chair allocated three minutes for public comment and called on the people who signed up in advance to speak, Tonia Sorrell-Neal, Pharmaceutical Care Management Association, and LuGina Mendez-Harper, of Prime Therapeutics. They provided testimony to the board.

Adjournment: The meeting was adjourned at 11:35 a.m. by Vice Chair Shelley Bailey, with a motion by **Rebecca Spain** and a second by **Richard Bruno**.

PORTAL
Program on Regulation, Therapeutics, And Law

DoPE

Oregon Prescription Drug Affordability Board Meeting

February 15, 2023

Program On Regulation, Therapeutics, And Law (PORTAL)
Division of Pharmacoepidemiology and Pharmacoeconomics
Department of Medicine,
Brigham and Women's Hospital and Harvard Medical School

HARVARD MEDICAL SCHOOL
TEACHING HOSPITAL

BRIGHAM HEALTH
BRIGHAM AND
WOMEN'S HOSPITAL

PORTAL
Program on Regulation, Therapeutics, And Law

DoPE BWH

The PORTAL Team

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Clinical Research Fellow

Catherine Huang, MD, MSPH
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Instructor in Medicine

Aaron Kesselheim, MD, JD, MPH
Professor of Medicine
Director

Jerry Avorn, MD
Professor of Medicine

Disclosures

- PORTAL receives grant funding the following sources:
  - Arnold Ventures, the Elevance Health Public Policy Institute, the Kaiser Permanente Institute for Health Policy, the Massachusetts Health Policy Commission, and the Commonwealth Fund.
- We do not receive any funding from pharmaceutical companies.

Summary

- Review Oregon PDAB's statutory authority under S.B. 844
  - Identifying eligible prescription drugs
  - Selecting drugs that pose an affordability challenge
  - Considerations and challenges
- Factors to use when determining whether drugs pose an affordability challenge
  - Price and use
  - Comparative cost and benefit
  - Affordability and access

Identifying Eligible Prescription Drugs

*"The Department of Consumer and Business Services shall provide to the Prescription Drug Affordability Board each calendar quarter a **list of prescription drugs** included in reports submitted to the department:"*

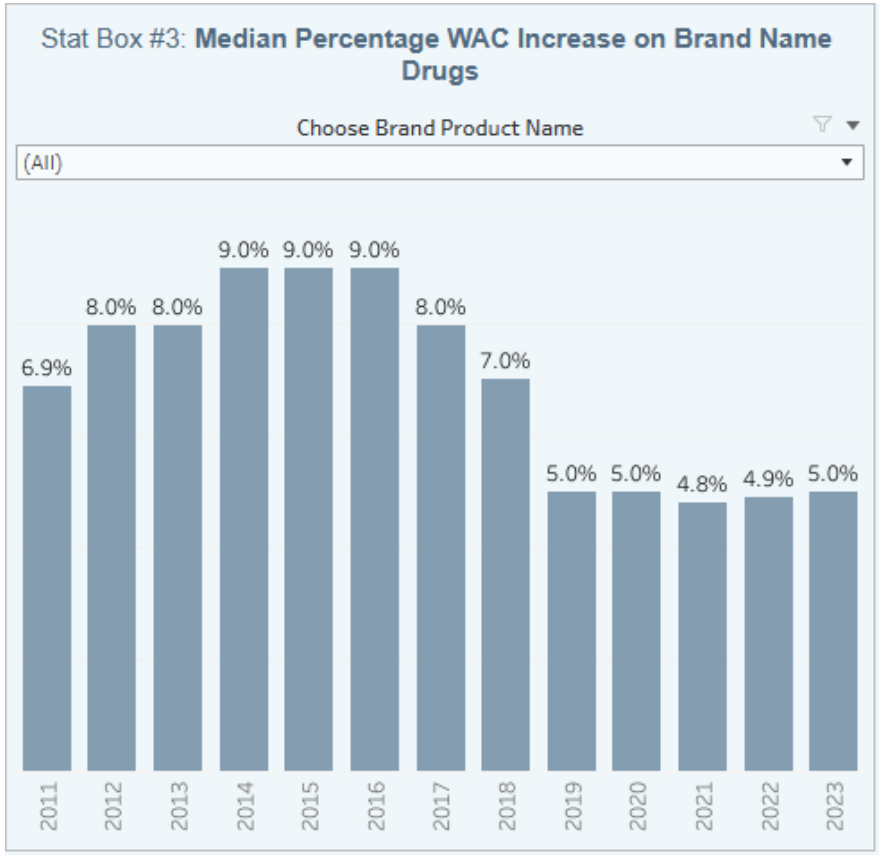
Manufacturer Reporting ORS 646A.689 (2) and (6)	Payer Reporting ORS 743.025	Insulins
• Price >$100 per one-month supply and >10% increase in previous year • Newly marketed with price higher than CMS specialty threshold ($830/mo in 2023)	• 25 most frequently prescribed drugs • 25 most costly drugs • 25 drugs with greatest increase in spending in past year	• All insulins marketed in Oregon in the prior year

Drugs with an FDA **Orphan Drug Act designation** for treating a rare disease are excluded

Eligible Prescription Drugs: Considerations

- In 2023, **zero drugs** have had annual price increases >10% (46Brooklyn)

- In 2021, the median WAC/year for newly marketed drugs was $180k
  (Rome et al. JAMA. 2022.)
  - 24 of 30 drugs were priced >$830/mo (the CMS specialty tier threshold)



https://www.46brooklyn.com/branddrug-boxscore

Excluding drugs for rare diseases?

- *"A drug that is designated by the Secretary of the United States Food and Drug Administration, under 21 U.S.C. 360bb, as a **drug for a rare disease or condition** is not subject to review under subsection (1) of this section.'*
- Under the Orphan Drug Act of 1983, the FDA may grant drugs **special designation** if they treat a condition that affects **<200,000 Americans**
- From 2008-2018, **41%** of newly approved drugs had Orphan designation (Darrow, Avorn, Kesselheim. *JAMA*. 2020)
- **Orphan designations are specific to a drug's indications;** many top-selling drugs have both orphan-designated and non-designated indications (Chua, Kimmel, Conti. *Health Affairs*. 2021)
- For example, **all 5 of the drugs with the highest spending in Oregon** in 2021 had an orphan designation
  - Only 1 drug is FDA approved for a single orphan-designated condition: Elexacaftor/Tezacaftor/Ivacaftor [Trikafta] for cystic fibrosis

Selecting Drugs that Pose Affordability Challenges

"Each calendar year, the board shall identify nine drugs and at least one insulin product…that the board determines may create affordability challenges for ***health care systems or high out-of-pocket costs for patients*** *in this state…"*

Selecting Drugs that Pose Affordability Challenges

High Out-of-Pocket Costs

- Includes only the costs paid by **patients using a drug**.
- Associated with lower medication adherence and poor clinical outcomes.
- 1 in 4 patients reports not taking medications as prescribed due to cost (KFF 2022).
- Costs depend on insurance plan design (copayments, coinsurance, deductibles)

High cost to the health care system

- Includes drug costs paid by **patients and insurers.**
- Ultimately leads to higher premiums, lower wages, and higher taxes for all residents.
- Might strain the state's budgets, resulting in fewer resources for other services (e.g. education, infrastructure)

Selecting Drugs that Pose Affordability Challenges

Each calendar year, the board shall identify nine drugs and at least one insulin product…that the board determines may create affordability challenges for health care systems or high out-of-pocket costs for patients in this state ***based on criteria adopted by the board by rule, including but not limited to:***

Price and use

- The number of residents prescribed the drug (b)
- Price of the drug, including manufacturer price concessions (e.g., rebates) to insurers/PBMs (c,d,e)
- Cost to insurers, based on use consistent with FDA labeling (h)

Comparative cost and benefit

- Price for therapeutic alternatives, including discounts/rebates (f,g)
- Relative financial impacts to health, medical, or societal services costs compared to therapeutic alternatives (j)

Affordability and access

- Average patient cost-sharing (k)
- Impact on access, based on insurance benefit design (i)
- Whether the prescription drug has led to health inequities in communities of color (a)

Other Information

- Any other information a manufacturer chooses to provide (L)
- Other factors determined adopted in rules by the board (m)

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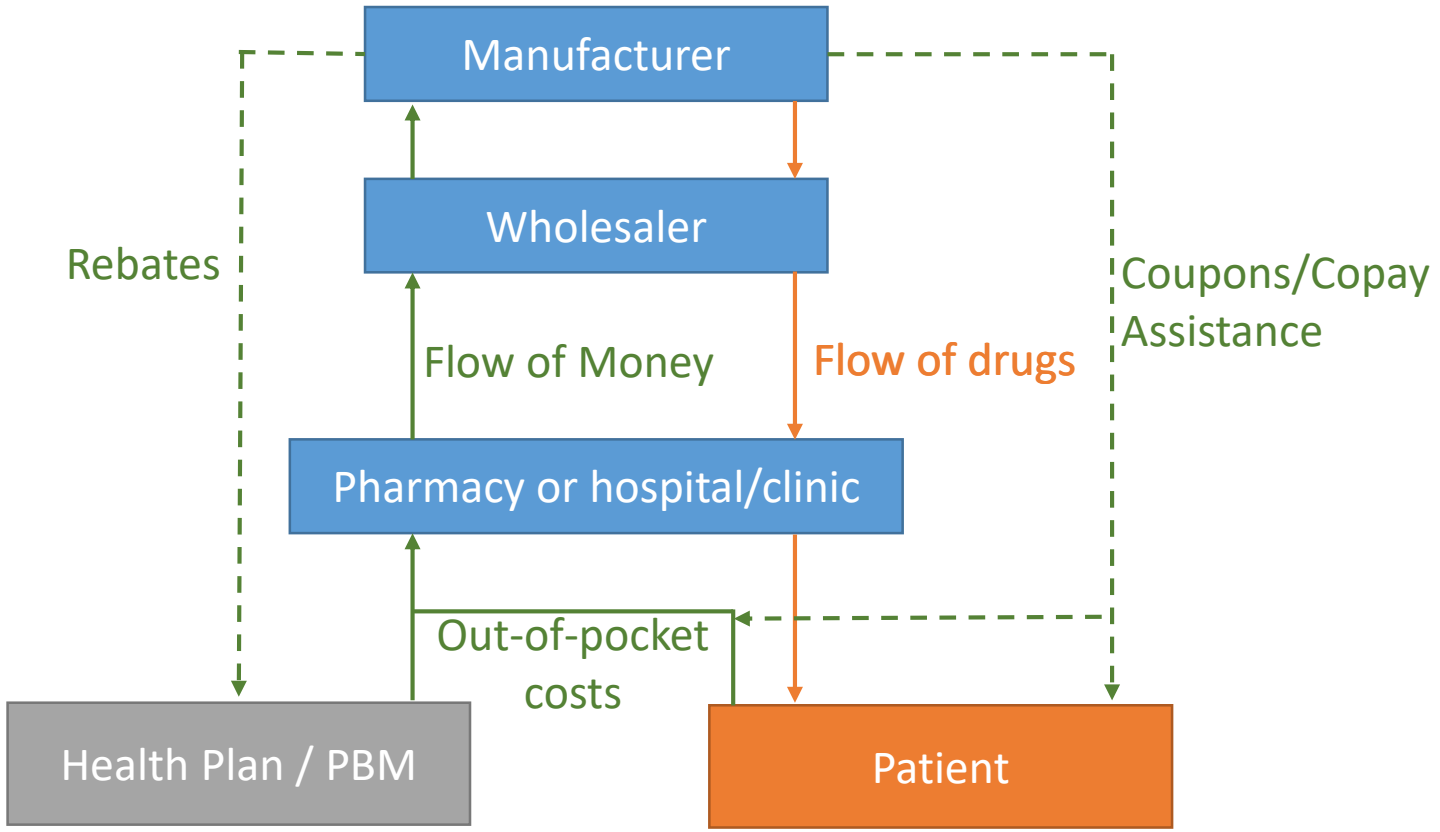
Pharmaceutical Supply Chain

1. Drug manufacturers set the **list price** (wholesale acquisition cost = WAC)

2. Health plans or pharmacy benefit managers (PBMs) set the formulary and **out-of-pocket costs**

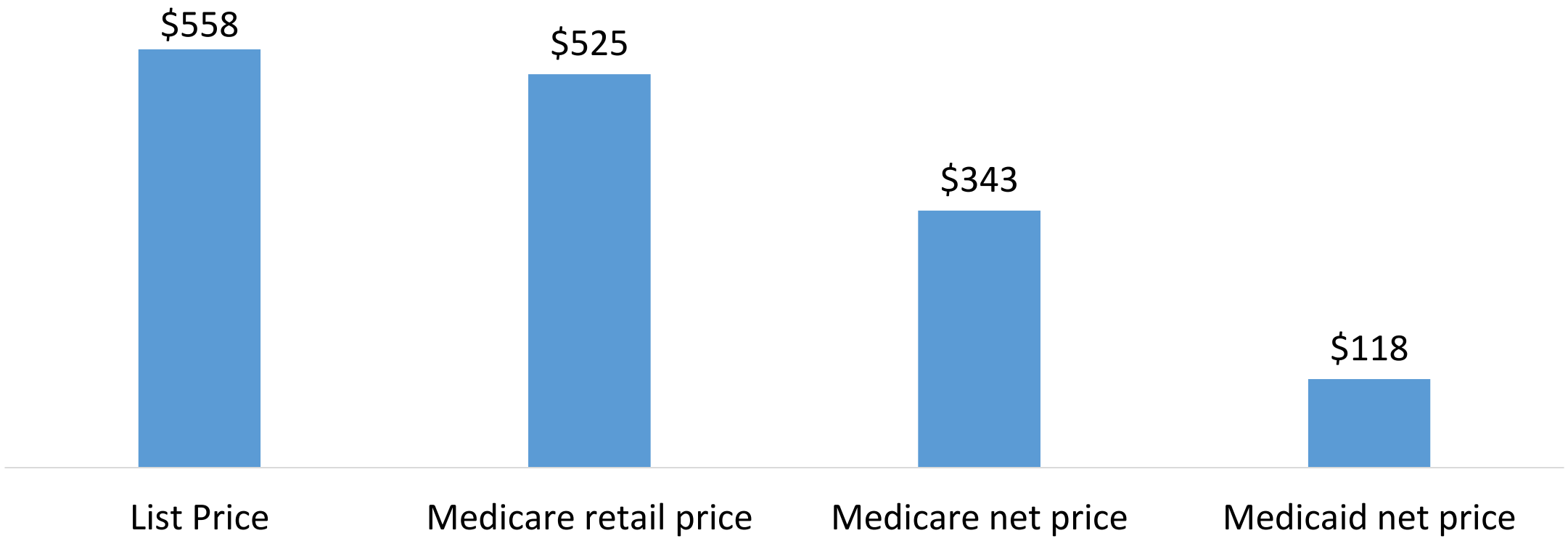
3. Health plans / PBMs negotiate **rebates** in exchange for preferred formulary position (↓ out-of-pocket costs)
   - **Net price** = list price - rebates

4. Drug manufacturers offer **coupons** to offset out-of-pocket costs charged by insurance.



Average Brand-name Drug Prices

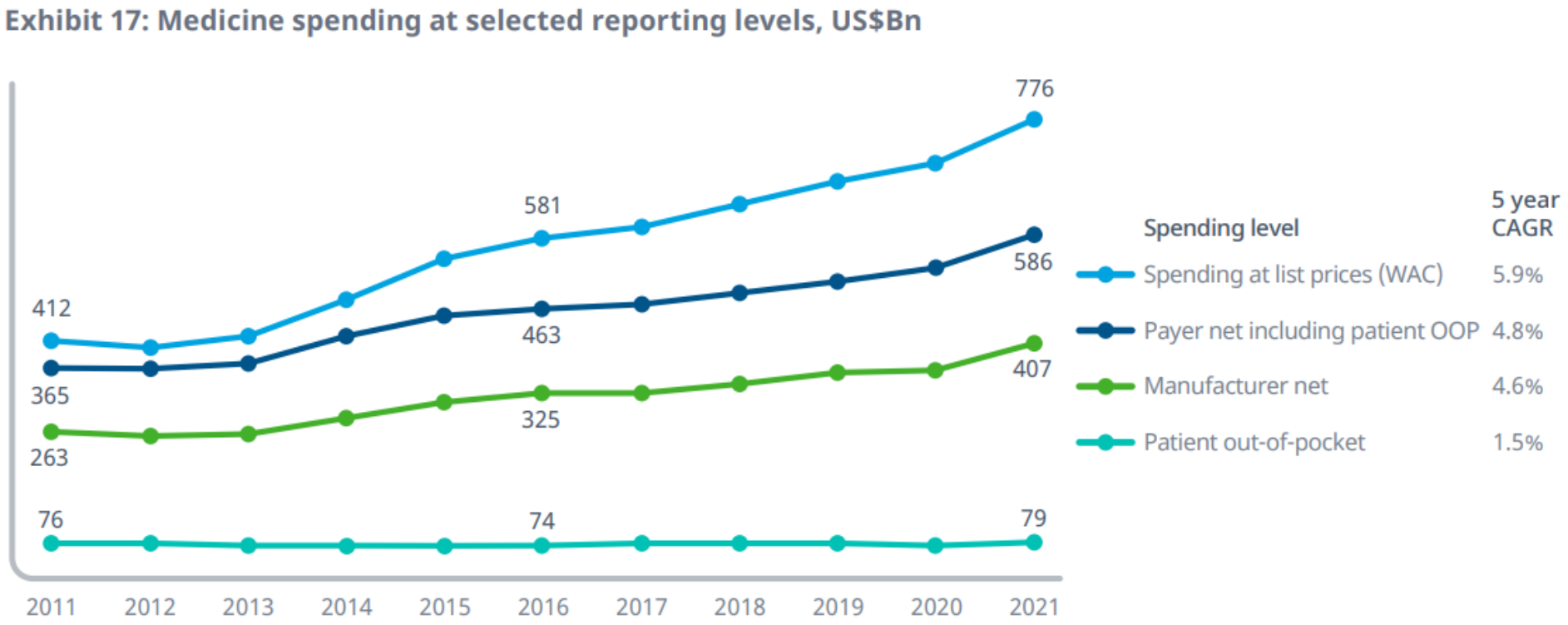
For 176 top-selling drugs in 2017



https://www.cbo.gov/publication/56978

Spending is Rising Using List and Net Prices

- Prices (WAC) increasing by 5.9% per year
- Net spending by patients and payers increasing by 4.8% per year



The IQVIA Institute. Medicine Spending and Affordability in the US. 2022.

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Measuring Drug's Benefit Compared to Therapeutic Alternatives

Factors to Consider

- Clinical effectiveness
- Side effects, interactions, contraindications
- Impact on health resource utilization (i.e., hospitalizations, other medications, caregiver burden)
- Ease of use (setting of administration, dosing frequency, duration of therapy)

Data Sources

- Premarket and post-market clinical trials
- Comparative effectiveness trials or meta-analyses
- Observational studies (real world evidence)
- FDA approval documents
- Existing health technology assessments
- Consultation with experts (clinicians) and patients

Measuring Drug's Benefit Compared to Therapeutic Alternatives

Need to consider both <u>amount</u> of benefit AND the <u>level of evidence</u> in the literature

Net Clinical Benefit

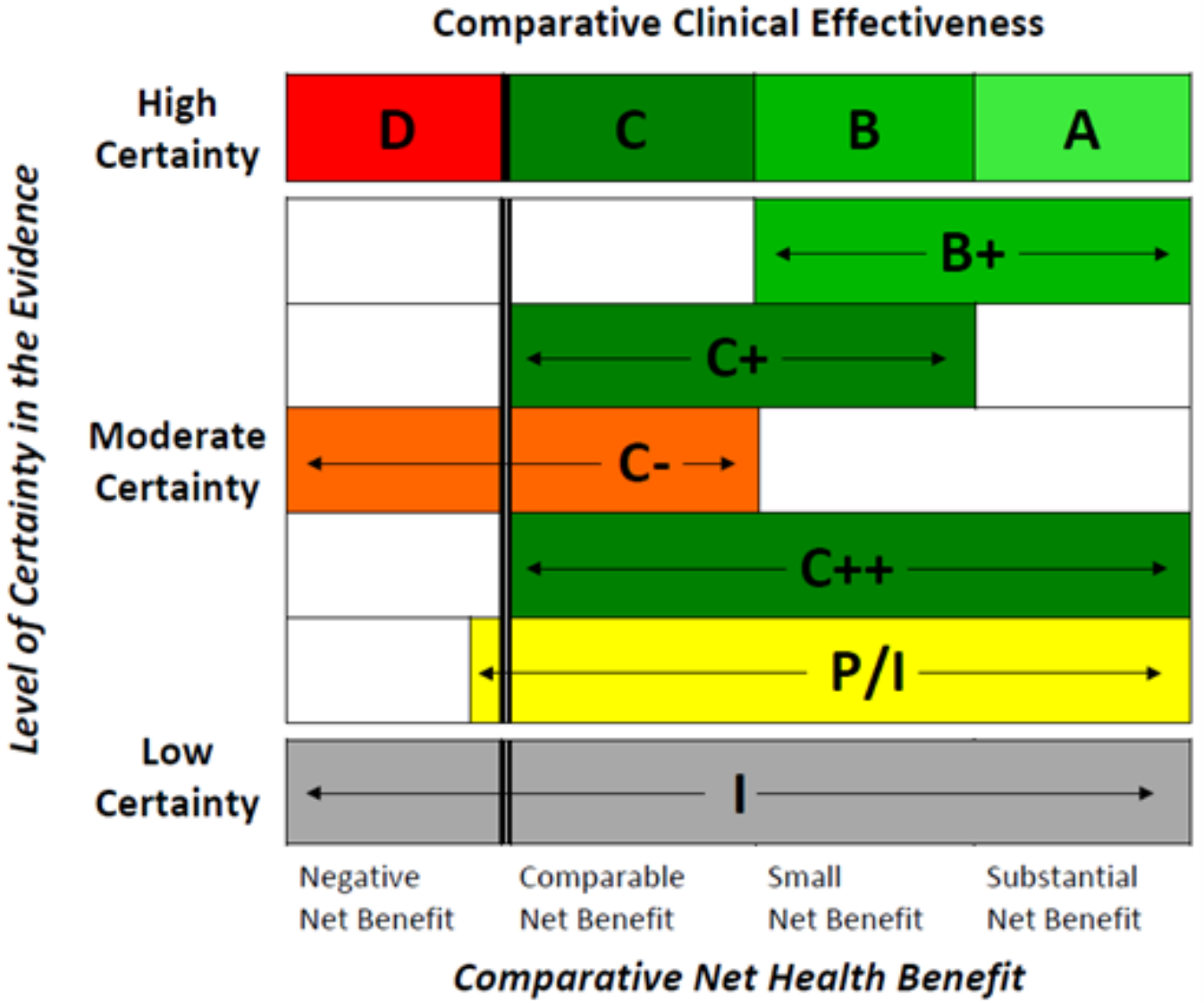
- Inferior
- None
- Minor Benefit
- Moderate Benefit
- Major Benefit

Quality of Evidence

Example: ICER Evidence Rating Matrix

A = "Superior"
B = "Incremental"
C = "Comparable"
D= "Negative"

B+= "Incremental or Better"
C+ = "Comparable or Incremental"
C- = "Comparable or Inferior"
C++ = "Comparable or Better"
P/I = "Promising but Inconclusive"
I = "Insufficient"



Mechanism for assessing comparative cost depends on the net clinical benefit

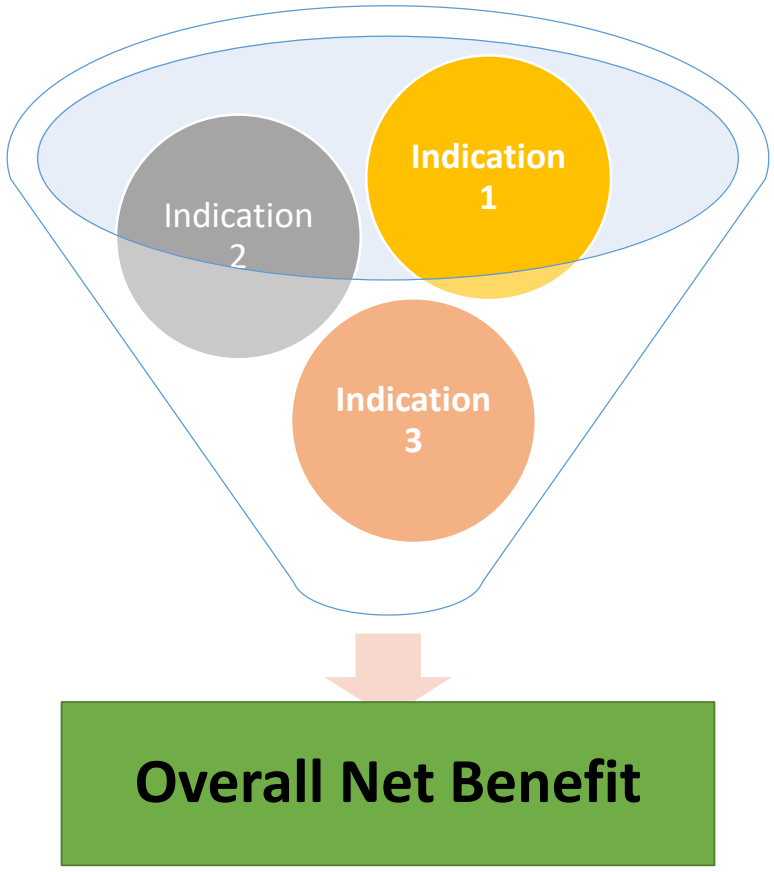
If drug offers **no or minor** added clinical benefit

- Can **reference** drug's price to therapeutic alternatives, assuming they are priced affordably

If drug **offers moderate or major** added clinical benefit

- Need to quantify **how much more we are willing to pay** for a drug's incremental benefit, compared to alternatives

Net comparative benefit may vary by indication



Factors to consider

- Net comparative benefit for each indication
- Prevalence of each indication
- How drug is used for each indication

Measuring Clinical Effectiveness

- **Gold Standard:** Increased **longevity and/or quality of life**
  - Examples of improved quality of life: Reducing pain, improved mobility, improved cognitive function
  - Quality of life typically measured using disease-specific metrics or symptom scales
- In some cases, **surrogates measures** may be used instead (e.g. Accelerated Approval pathway drugs)
  - Examples: Hemoglobin A1c, LDL, progression free survival
  - Need to consider strength of evidence supporting the surrogate measure in predicting clinical outcomes.

Measuring Cost Effectiveness

- Evaluate **costs** and **health benefits** of 2 or more alternative treatments (e.g., drug A vs drug B)
- **Costs** include treatment costs plus downstream costs / savings
  - Includes **health care costs** (e.g. hospitalizations averted)
  - Can also include **societal costs** or savings (e.g. productivity), although difficult to measure so introduces uncertainty
- The resulting incremental cost effectiveness ratio (ICER) can be applied to an explicit threshold or as a means of negotiating price

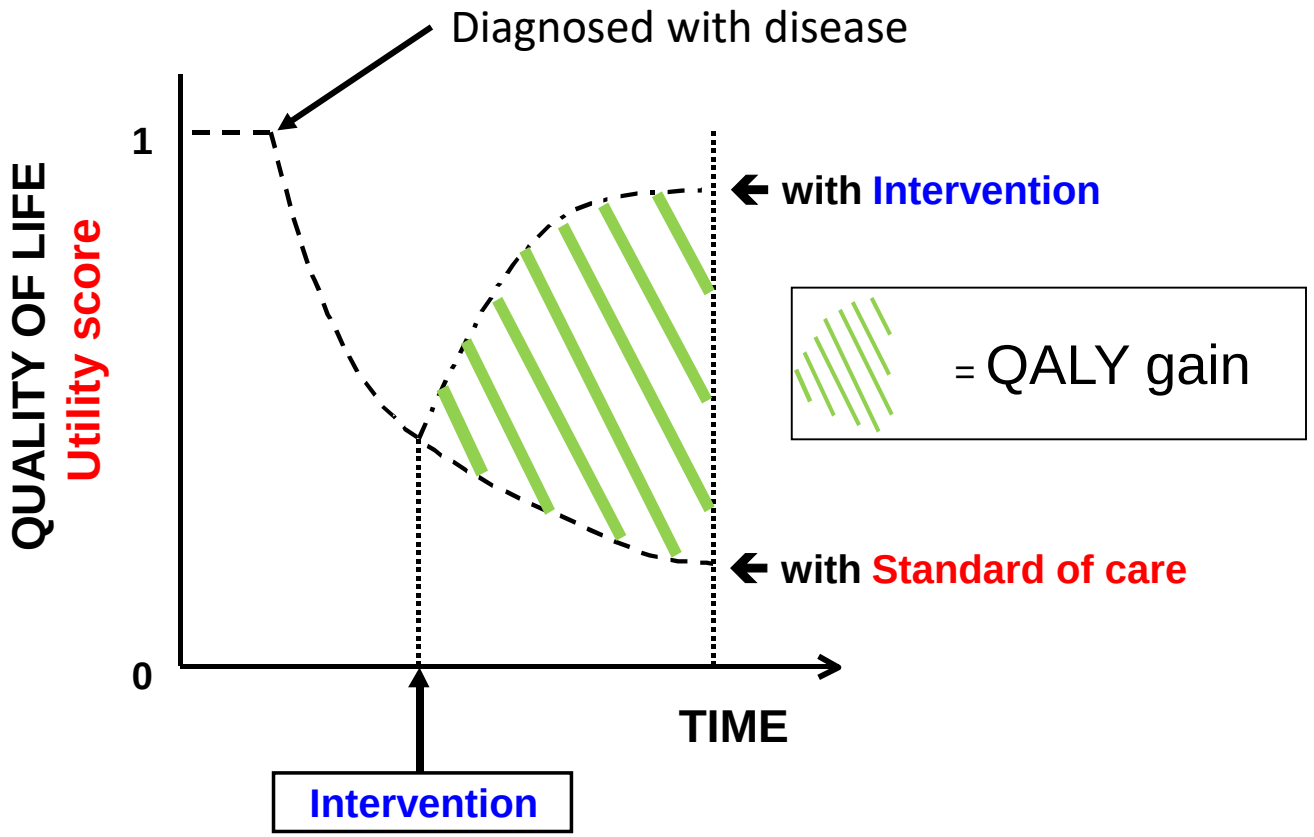
$$\textbf{Incremental Cost Effectiveness Ratio (ICER)} = \frac{\text{Costs}_{\text{New}} - \text{Costs}_{\text{Current}}}{\text{Benefits}_{\text{New}} - \text{Benefits}_{\text{Current}}}$$

Sanders, et al. Second Panel on CEA in Health and Medicine. *JAMA*. 2016.

Quality-Adjusted Life Years (QALYs)

- *"If the board considers the cost-effectiveness of a prescription drug in criteria adopted by the board under subsection (1) of this section, the board* ***may not use quality-adjusted life-years, or similar formulas that take into account a patient's age or severity of illness or disability, to identify subpopulations for which a prescription drug would be less cost-effective****. For any prescription drug that extends life, the board's analysis of cost effectiveness* ***must weigh the value of the quality of life equally*** *for all patients, regardless of the patients' age or severity of illness or disability."*

QALYs (with and without intervention)



- QALY = duration * health-related quality of life (HRQoL)
- The QALY is intended to be used as incremental/comparative measure of benefit
  - i.e., used within the same disease to determine the incremental effect of a drug
- In the example, all patients have the same disease, the differential effect on QALYs is due to treatment

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Other measurements of health benefit in CEA

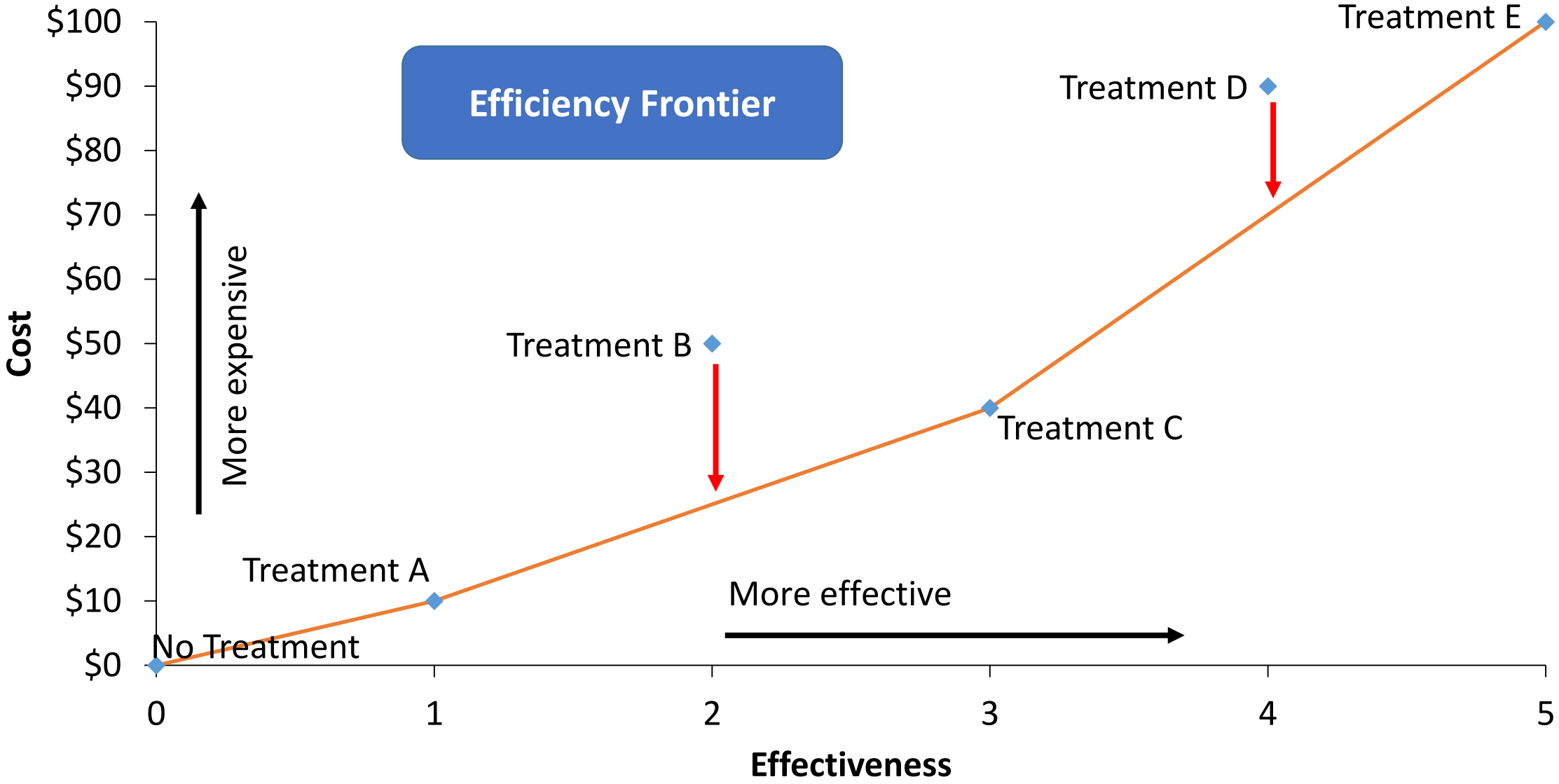
- **Life years gained (LYG)** - estimating gains in survival between the two treatment arms (no weighting applied).
  - Most cost-effectiveness analyses report both QALY and LYG outcomes

- **Equal value life year gained (evLYG)** – applies the same weighting (0.851) to estimated gains in survival between the two arms, reflecting average health.
  - This measure was developed by the Institute for Clinical and Economic Review (ICER)

- **'Natural' units –** Disease-specific outcome measurements
  - May be measured directly in clinical trials
  - E.g., biomarker, surgeries avoided, hospitalizations avoided

Efficiency Frontiers

- Compares price and effectiveness of drug with therapeutic alternatives
- Most useful if there are several (>2) treatment alternatives
- Can still model long-term costs (including savings) and health benefits of each drug
- **Benefit:** Can use disease-specific measurements of health benefits
  - No need for standardization across diseases types
- **Limitation:** Assumes that comparator treatments are priced affordably


Efficiency Frontier
Cost
$100
$90
$80
$70
$60
$50
$40
$30
$20
$10
$0
More expensive
Treatment E
Treatment D
Treatment B
Treatment C
Treatment A
No Treatment
More effective
0
1
2
3
4
5
Effectiveness

Cost effective drugs may be unaffordable

- **Cost-effective drugs may still be considered unaffordable due to high budgetary impact.**

- **Budget impact analysis** is an analytical method that incorporates actual cost to the health system, considering issues around price/cost, volume, market uptake, displaced alternatives, etc.

- Example: Hepatitis C Antivirals
  - Despite high price tag ($80k/treatment course), they are highly-cost effective (Najafzadeh et al. *Annals Int Med.* 2015).
  - But given the large number of patients in need of treatment, Medicaid programs faced severe budget shortfalls, leading states to severely restrict access

Selecting Drugs that Pose Affordability Challenges

Each calendar year, the board shall identify nine drugs and at least one insulin product…that the board determines may create affordability challenges for health care systems or high out-of-pocket costs for patients in this state ***based on criteria adopted by the board by rule, including but not limited to:***

Price and use

- The number of residents prescribed the drug (b)
- Price of the drug, including manufacturer price concessions (e.g., rebates) to insurers/PBMs (c,d,e)
- Cost to insurers, based on use consistent with FDA labeling (h)

Comparative cost and benefit

- Price for therapeutic alternatives, including discounts/rebates (f,g)
- Relative financial impacts to health, medical, or societal services costs compared to therapeutic alternatives (j)

Affordability and access

- Average patient cost-sharing (k)
- Impact on access, based on insurance benefit design (i)
- Whether the prescription drug has led to health inequities in communities of color (a)

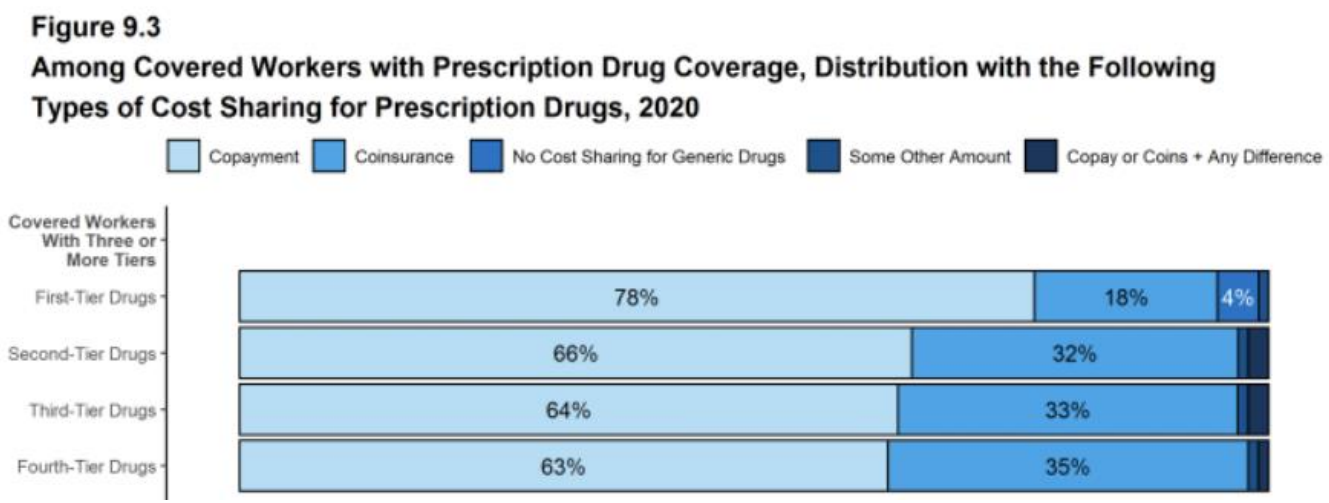
Other Information

- Any other information a manufacturer chooses to provide (L)
- Other factors determined adopted in rules by the board (m)

High costs may limit access

- High **out-of-pocket costs** may limit patient's ability to afford medications
  - E.g. deductibles, copayment, coinsurance
- Payers may enact **utilization management** tools to restrict access to high-cost medications:
  - **Formulary exclusions** - Rare, but getting more common for commercial insurers. Public payers have more limited ability to do this.
  - **Prior authorization** – Requiring payer approval before a drug is prescribed
  - **Step therapy** – Requiring patient to try a less expensive alternative first

Typical Out-of-Pocket Costs with Private Insurance



Tier	Average copayment	Average coinsurance
1 (Generic)	$11	18%
2 (Preferred brand)	$35	25%
3 (Non-preferred brand)	$62	37%
4 (Specialty)	$116	28%

KFF 2020 Employer Health Benefit Survey
https://www.kff.org/report-section/ehbs-2020-section-9-prescription-drug-benefits/

Out-of-pocket costs and health inequities

- Patients with myocardial infarction randomized to **usual care** vs. **zero out-of-pocket costs** for cardiovascular medications (statin, beta blocker, ACE inhibitor/ARB)
- Medication adherence improved in all patients…
- But cardiovascular outcomes improved only among non-White patients

The NEW ENGLAND JOURNAL of MEDICINE

SPECIAL ARTICLE

Full Coverage for Preventive Medications after Myocardial Infarction

Niteesh K. Choudhry, M.D., Ph.D., Jerry Avorn, M.D., Robert J. Glynn, Sc.D., Ph.D., Elliott M. Antman, M.D., Sebastian Schneeweiss, M.D., Sc.D., Michele Toscano, M.S., Lonny Reisman, M.D., Joaquim Fernandes, M.S., Claire Spettell, Ph.D., Joy L. Lee, M.S., Raisa Levin, M.S., Troyen Brennan, M.D., J.D., M.P.H., and William H. Shrank, M.D., M.S.H.S., for the Post-Myocardial Infarction Free Rx Event and Economic Evaluation (MI FREEE) Trial

DISPARITIES

By Niteesh K. Choudhry, Katsiaryna Bykov, William H. Shrank, Michele Toscano, Wayne S. Rawlins, Lonny Reisman, Troyen A. Brennan, and Jessica M. Franklin

Eliminating Medication Copayments Reduces Disparities In Cardiovascular Care

DOI: 10.1377/hlthaff.2013.0654
HEALTH AFFAIRS 33,
NO. 5 (2014): 863–870

Summary

- S.B. 844 allows the PDAB to review the affordability of certain drugs, including new specialty drugs and current top-selling drugs.
- Drugs may be unaffordable to the health care system, to patients via high-out-of-pocket costs, or both.
- In selecting drugs that are unaffordable, the PDAB must consider multiple criteria, including:
  - the cost and use of the drug in Oregon;
  - the comparative cost and benefit, relative to therapeutic alternatives; and
  - how cost is impacting affordability, access, and equity

Questions?

Oregon Prescription Drug
Affordability Board

Prescription Drug Affordability Board

Generic drug report draft outline

Cortnee Whitlock
Board Policy Analyst

2023 generic drug report timeline

February 15 PDAB Meeting	March 15 PDAB Meeting	April 19 PDAB Meeting	May 17 PDAB Meeting	June 1 Report Due
Present draft outline to board	Present draft report to board	Present draft report edits to board	Board approval of final draft	Send report to the Oregon Legislature

*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

What's new in the 2023 generic drug report

2022 report

- ✓ Introduction
- ✓ Biologics and biosimilars
- ✓ Generic drug pricing cost, utilization
- ✓ Study of generic drugs
- ✓ Impact on generic drug market
- ✓ Generic shortages
- ✓ Conclusion

2023 report

Foundation of 2022 report
+ Oregon data
+ Biosimilars expanded
+ Price inflation on brand drugs
+ What else?

= 2023 report

Oregon Prescription Drug
Affordability Board

Prescription Drug Affordability Board

Fee structure rule draft outline

Cortnee Whitlock
Board Policy Analyst

PDAB rulemaking timeline

Fee structure

- Board discussion: Feb. 15 and March 15
- Rulemaking advisory committee: March 22
- Board approval: April 19
- File with Secretary of State: April 25
- Public hearing: May 22
- Board final approval: June 21
- File with Secretary of State: June 26
- Effective date: July 1, 2023

Affordability review

- Board discussion: Feb. 15 and March 15
- Rulemaking advisory committee: March 22
- Board approval: April 19
- File with Secretary of State: April 25
- Public hearing: May 22
- Board final approval: June 21
- File with Secretary of State: June 26
- Effective date: July 1, 2023

Oregon Prescription Drug
Affordability Board

Prescription Drug Affordability Board

Affordability review draft outline

Cortnee Whitlock
Board Policy Analyst

Affordability review rule draft outline

Select eligible drugs for review

DCBS will provide a list. PDAB will consider:

* Class of prescription drug and therapeutic equivalents

*Aggregated data

*Average patient out-of-pocket cost

Conduct affordability review

Based on criteria from ORS 646A.694 and board member discussion, expertise

Identify 9 drugs, 1 insulin

Prescription drugs and insulin product that may create affordability challenges for health care systems or high, out-of-pocket costs for patients in Oregon

Write report for the Oregon Legislature by Dec. 31, 2023

Report includes:

* Price trends

* Reviewed drugs

* Recommendations

Confidentiality

PDAB will not disclose confidential, trade secret, or proprietary information

Affordability review draft criteria

Statute

Board Feedback

- Has the prescription drug led to health inequities in communities of color
  - Include as a separate criteria pharmacy deserts because it impacts access to medication
  - Use the language “under resourced communities”
- Number of Oregonians prescribed the drug
  - Consider using the term individuals rather than residents because some non-residents receive care in Oregon
  - Include off label use (prescription drugs used to treat other conditions)
- Price of the prescription drug sold in Oregon
  - All drugs sold in Oregon or only new drugs in 2022?
- Price and availability for therapeutic alternatives and changes over time
- Rebates, discounts, price concessions from manufacturer for health insurance plans, pharmacy benefit managers, or consumers
- Average patient copayment, deductible, or other cost-sharing for the prescription drug
- Financial impact to health, medical, or social services costs compared to costs of therapeutic alternatives
  - * PDAB may not use quality-adjusted life year analysis to evaluate financial effects

Affordability review draft criteria

Statute

Board Feedback

- Cost to health insurance plan based on patient use of the drug
  - What medical or other expenses do the drugs help offset?
  - What is the drug's target population?
  - Consider, orphan drugs that treat rare diseases
- Impact on patient access to the drug
  - Look at adjudicated claims (medications filled versus prescribed)
  - Diagnosis codes may be helpful
- Impact on 340Bs and other safety net providers
- Testimony from patients, caregivers, scientific or medical experts, and others
  - Reach out to medical providers to encourage patient testimony
- Any information manufacturer, carrier, pharmacy benefit manager, or others choose to provide
- Information from Oregon Health Authority and others
- Non-adherence utilization management information
- Research related to introductory prices or price increases

DRAFT OUTLINE

Affordability Reviews for Eligible Prescription Drugs

(1) The purpose of this rule is to establish the methodology and process for the Prescription Drug Affordability Board (PDAB) to annually conduct an affordability review that identify nine prescription drugs and at least one insulin product that may create affordability challenges for health care systems or high out-of-pocket costs for patients in Oregon.

(2) **Eligible Prescription Drugs for Affordability Reviews**

Each calendar quarter PDAB will be provided from the Department of Consumer and Business Services a list of prescription drugs included in reports submitted to the department under ORS 646A.689 (2) and (6), a list of drugs included in reports submitted to the department under ORS 743.025, and a list of insulin drugs marketed in this state during the previous calendar year. From these lists, annually PDAB will identify nine drugs and at least one insulin product through an affordability review.

(3) **Selecting Prescription Drugs for Affordability Reviews**

PDAB will select from the eligible prescription drugs in subsection (2) a subset of drugs to prioritize for an affordability review under subsection (4) of this rule, by considering the following:

(a) Class of the Prescription Drug and Therapeutic Equivalents:

(A) Determine the date of FDA approval of the eligible prescription drug and whether the prescription drug was approved through an expedited pathway.

(B) For brand-name drugs and biological products, determine the class and whether there are any approved and marketed generic drugs or biosimilar drugs for the specific brand-name drug or biological product.

(C) Where there are therapeutic equivalents, PDAB may consider for each equivalent the cost and availability by considering utilization data and spending data.

(b) Aggregated Data:

(A) Health equity impact, including whether the prescription drug is utilized to treat a condition disproportionately experienced by priority populations;

(B) Historical and current pricing data, including wholesale acquisition cost and average sales price of the prescription drug;

(C) Expenditures associated with the prescription drug, including expenditures identified in APAC data;

(D) Utilization associated with the prescription drug, including utilization identified in APAC data; and

(E) Information regarding the estimated manufacturer net-cost and net-sales amounts for eligible prescription drugs.

(c) Average Patient Out-Of-Pocket Cost: Consideration of the average patient out-of-pocket cost for the prescription drug, which may include copayment amounts, cost-sharing amounts, coinsurance amounts, and other information relevant to out-of-pocket costs.

(4) **Conducting an Affordability Review**

PDAB will conduct an affordability review on the prioritized subset of prescription drugs selected under subsection (3) to identify nine prescription drugs and at least one insulin product that may create affordability challenges for health care systems or high out-of-pocket costs for patients in Oregon.

(a) PDAB will conduct an affordability review by considering, to the extent practicable, the following criteria set forth in ORS 646A.694:

(A) Whether the prescription drug has led to health inequities in communities of color;

(B) The number of residents in this state prescribed the prescription drug;

(C) The price for the prescription drug sold in this state;

(D) The estimated average monetary price concession, discount or rebate the manufacturer provides to health insurance plans in this state or is expected to provide to health insurance plans in this state, expressed as a percentage of the price for the prescription drug under review;

(E) The estimated total amount of the price concession, discount or rebate the manufacturer provides to each pharmacy benefit manager registered in this state for the prescription drug under review, expressed as a percentage of the prices;

(F) The estimated price for therapeutic alternatives to the drug that are sold in this state;

(G) 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;

(H) 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;

(I) The impact on patient access to the drug considering standard prescription drug benefit designs in health insurance plans offered in this state;

(J) The relative financial impacts to health, medical or social services costs as can be quantified and compared to the costs of existing therapeutic alternatives;

(K) The estimated average patient copayment or other cost-sharing for the prescription drug in this state; and

(L) Any information a manufacturer chooses to provide.

(b) PDAB conducts an affordability review by considering, to the extent practicable, the additional following criteria:

(A) In addition to the criteria in subparagraph (a)(A): Health Equity Factors: Whether the pricing of the prescription drug results in or has contributed to health inequities in under resourced communities and pharmacy deserts.

(B) In addition to the criteria in subparagraph (a)(B): Include off label use of prescription drugs used to treat other conditions.

(C) Current wholesale acquisition cost of the prescription drug and changes in the prescription drug's wholesale acquisition cost over time.

(D) In addition to the criteria in subparagraph (a)(C): Cost and availability of therapeutic alternatives to the prescription drug in the state, including any relevant data regarding costs, expenditures, availability, and utilization related to the prescription drug and its therapeutic alternatives.

(E) Price Effect on Oregon Consumer Access: Effect of price on consumers' access to the prescription drug by reviewing changes in pricing, expenditure, and utilization over time.

(F) In addition to the criteria in subparagraph (a)(J): Relative Financial Effects of the Prescription Drug on Health, Medical, or Social Services Costs:

i. To the extent such information can be quantified, the relative financial

effects of the prescription drug on broader health, medical, or social services costs, compared with therapeutic alternatives or no treatment.

ii. Identify if the sources it relies on use a quality-adjusted life-year analysis or a similar formula that takes into account a patient's age or severity of illness or disability, to identify subpopulations for which a prescription drug would be less cost-effective. PDAB may not use quality-adjusted life year analysis or a similar formula to evaluate relative financial effects.

(G) In addition to the criteria in subparagraph (a)(K): Patient copayment or other cost sharing data, across different health benefit plan designs, to the degree such information is available in the APAC, including:

i. Copayment;

ii. Coinsurance;

iii. Deductible; and/or

iv. Any other copayment and cost sharing data.

(H) Impact on Safety Net Providers: When the prescription drug is available through section 340B of the federal Public Health Service Act (42 U.S.C. 256b):

i. Information regarding safety net providers participating in the 340B, including information to assist with gathering input to assess the impact to safety net providers for a prescription drug under review that is available through Section 340B of the Federal "Public Health Service Act", Pub.L. 78-410;

ii. The utilization of the prescription drug by the safety net provider's patients;

iii. Whether the safety net provider receives a 340B discount for the prescription drug;

iv. Where the safety net provider does not receive a discount, whether access to the prescription drug is impeded; and

v. Any other topics identified by safety net provider stakeholders for discussion.

(I) Input from Specified Stakeholders:

i. Patients and Caregivers

1. Seek input from patients and caregivers affected by a condition or disease that is treated by the prescription drug under review by gathering information related to:

a) The impact of the disease,

b) Patient treatment preferences,

c) Patient perspective on the benefits and disadvantages of using the prescription drug,

d) Caregiver perspective on the benefits and disadvantages of using the prescription drug, and/or

e) Available patient assistance in purchasing the prescription drug.

2. In seeking additional information, attempt to gather a diversity of experience among patients from different socioeconomic backgrounds.

ii. Individuals with Scientific or Medical Training: Seek input from individuals who possess scientific or medical training with respect to a condition or disease treated by the prescription drug that is under review by PDAB, including:

1. The impact of the disease,

2. Perspectives on benefits and disadvantages of the prescription drug, including comparisons with therapeutic alternatives if any exist, and/or

3. Input regarding the prescription drug utilization in standard medical practice, as well as input regarding off label usage.

(J) Rebates, Discounts, and Price Concessions:

i. To the extent practicable, estimated manufacturer net-sales or estimated net-cost amounts (including rebates, discounts, and price concessions) for the prescription drug and therapeutic alternatives; and

ii. Manufacturer financial assistance the manufacturer provides to pharmacies, providers, consumers, and other entities.

(K) Information from the Oregon Health Authority (OHA), Health Evidence Review Commission (HERC), and Pharmacy and Therapeutics Committee (P&T):

i. Additional analyses conducted that is relevant to the prescription drug or therapeutic alternative under review.

(L) Non-adherence and Utilization Management Information: Information regarding non-adherence to the prescription drug, as well as information related to utilization management restrictions placed on the prescription drug.

(M) PDAB may consider any document and research related to the introductory price or price increase of a prescription drug, including life cycle management, net average price in this state, market competition and context, projected revenue and the estimated value or cost-effectiveness of the prescription drug.

(c) After consideration of the criteria in subparagraphs (a) and (b), PDAB shall identify nine prescription drugs and at least one insulin product that may create affordability challenges for health care systems or high out-of-pocket costs for patients in Oregon.

(d) Report of Affordability Review: No later than December 31 of each year, PDAB shall include in its report to the Health Care Cost Growth Target program established in ORS 442.386 and to the interim committees of the Legislative Assembly related to health the prescription drugs that were reviewed under this rule with the following information:

(A) Price trends for the list of prescription drugs provided to the board by the Department of Consumer and Business Services under ORS 646A.694 (1);

(B) The prescription drugs that were reviewed under ORS 646A.694 (1); and

(C) Recommendations, if any, for legislative changes necessary to make prescription drug products more affordable in this state.

(e) Confidentiality:

(A) To the extent the information submitted to PDAB contains confidential, trade secret or proprietary information, PDAB will meet in executive session to discuss the information pursuant to ORS 192.660.

(B) PDAB will not disclose confidential, trade secret or proprietary information in an open meeting, its public meeting materials, or any reports.

(C) A manufacturer, carrier, pharmacy benefit manager, or other entity that voluntarily submits information for PDAB's consideration shall clearly designate the specific information it deems to be confidential, pursuant to ORS 192.355(4).