Oregon Prescription Drug Affordability Board

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Agenda

Date: **April 19, 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; Dr. 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; Amanda Claycomb, research analyst; Melissa Stiles, administrative specialist; Jake Gill, 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
☐ Presentation by: ICER Questions from board members	Sarah Emond, EVP and COO	25 minutes
☐ Legislative update	Jessie O'Brien	10 minutes
☐ Rulemaking Advisory Committee (RAC) update	Cortnee Whitlock	5 minutes
☐ Board discussion of draft rule for filing Affordability review	Cortnee Whitlock	45 minutes
☐ Board discussion Generic drug draft report	Cortnee Whitlock	5 minutes
☐ Announcements	Staff	5 minutes
☐ Public comment	Chair Patterson	10 minutes
☐ Adjournment	Chair Patterson	2 minutes

Next meeting

May 17, 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 decisions will be made in executive session. The board will make decisions only in sessions open to the public.

News Media: Representatives of the media wishing to attend executive session should call Jason Horton, 503-798-6376, with their name and news organization. Members of the news media are directed not to report on or otherwise disclose anything said during the executive session.

Oregon Prescription Drug Affordability Board

Oregon Prescription Drug Affordability Board Meeting
Wednesday, March 15, 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. Richard Bruno, Dr. Amy Burns, Dr. Daniel Hartung, Robert Judge (alternate), John Murray (alternate), Dr. Rebecca Spain (alternate).
Board members absent: None

Approval of the minutes: Chair Akil Patterson asked if board members had any changes to the Feb. 15, 2023, minutes on Pages 3-6 in the agenda packet: https://dfr.oregon.gov/pdab/Documents/20230315-PDAB-document-package.pdf and there were none. **Vice Chair Shelley Bailey** moved to approve the minutes and **Daniel Hartung** provided a second.

MOTION by Shelley Bailey to approve the Feb. 15, 2023 minutes.
Board Vote:
Yea: Richard Bruno, Amy Burns, Daniel Hartung, Shelley Bailey, Akil Patterson
Nay: None.
Motion passed.

Program update: Executive Director Ralph Magrish said staff met with guests from Health Care for All Maryland and John Mullen, chair of the OregonCoalition for Affordable Prescritpions (OCAP), to talk about their coalition building experience. Ralph reported that legislative counsel is working on an amendment to Senate Bill 404, which includes the board's recommendations. Staff is recruiting for a data analyst position, which closes March 20. DCBS will hold a rulemaking advisory committee (RAC) for the PDAB rules on March 29. Chair Akil Patterson and Ralph Magrish met with the Pharmaceutical Care Management Association (PCMA) and have extended an invitation to present during a board meeting this summer. The Institute for Clinical and Economic Review (ICER) will give a presentation to the board in April about how they approach clinical evidence using available data sources. PDAB holds a user license with ICER and will use the information during the board's affordability review process. Staff is preparing a contract with Jane Horvath of Horvath Healthcare, a policy consultant who will provide technical assistance and knowledge to the board. Staff is also preparing a solicitation for a technical assistance contractor to help with the affordability reviews.

Marty Carty, governmental affairs director, Oregon Primary Care Association, gave a presentation from Pages 7-20 in the agenda document about federally-qualified health centers (FQHC) and shared a video about OPCA. In Oregon, 34 organizations operate 270 care delivery sites that provide integrated primary and behavioral health care. Last year they served 430,000 patients, 40 percent identifying as a racial or ethnic minority. Section 340B of the Public Health Services Act requires drug manufacturers who participate in the Medicaid program to offer certain outpatient drugs to covered entities at discounted prices and provide the drug to patients based on a sliding fee scale. The same drug purchased at a discount is reimbursed at full price by payers when a patient has insurance. Covered entities retain the difference. FQHCs are required by statute to reinvest that difference into services that directly benefit patients. Under the Affordable Care Act in 2010, hospital organizations were added to the program as eligible covered entities but do not have to reinvest the net dollars back into programs and

patients. OPCA recommends making it easier for FQHCs to operate retail pharmacies, increased PBM regulations, and more flexibility in using a contract pharmacy.

Questions from the board: Robert Judge said FQHCs play a critical role, especially in rural Oregon. Pharmacy benefit managers (PBMs) are involved in the third-party payer of insured patients. What are the pain points FQHCs are seeing? **Marty Carty** said PBMs contract with safety net providers, particularly 340Bs covered entities, and reimburse them at a different rate than they do others. Oregon statute prohibits this yet the practice continues. Congress created the 340B program as a way to pay for health care for underserved populations without public money. When outside entities retain some of those dollars the covered entity is entitled to, they are undermining the safety net. **Robert Judge** said the dilemma is who ultimately is responsible for the cost of medications and paying for those services. The safety net provides a critical role. It is a Gordian knot, he said.

John Murray said he is a board member for the Morrow County Health District, which operates a critical access hospital and school-based health care center in rural Oregon. He is also a pharmacy owner of two critical access pharmacies in Eastern Oregon. He understands about PBMs trying to reduce reimbursement for any 340B claims because he experiences this in his own contracting. It hurts no one but the covered entity to have a drastically-reduced difference in pricing. Critical access hospitals and school-based clinics provide equal care for those populations having a difficult time, usually the poor in the rural areas. He is concerned about covered entities and pharmacies being left out because they are not listed as an FQHC. **Marty Carty** said OPCA wants to protect all safety net providers, particularly FQHCs. He said OPCA would never do anything that would have a negative impact on access to care for underserved communities.

Richard Bruno said he works at FQHCs through Central City Concern in Portland. Central City uses the 340B programs extensively to ensure they can get the right medications to their patients. Often times, those folks have extreme poverty and sometimes can't even afford a sliding scale $20 copay. Central City tries to provide medications at no cost through the 340B program, knowing the importance of patients getting their insulin or anti-diabetic medications. Central City is always thinking about how, as an organization and 340B pharmacy, to make this sustainable. He asked about the stability of the 340B program.

Marty Carty said he thinks the 340B program is on unstable footing. The New York Times and Washington Post published uncomfortable stories around the 340B program, though those were not FQHCs in those stories. When Congress created the 340B program, it did not authorize Health Resources and Service Administration power to promulgate rules, leaving it up to interpretation by consumers, or even Pharma, to create the rules of the road, he said. This program benefits the safety net, underserved communities and Congress needs to figure out a way to shore it up in a way that makes sense, he said.

Vice Chair Shelley Bailey said related to 340B and contract pharmacy relationships, sometimes there are unintended consequences for the pharmacy. As PBMs go through their contracting process and with the National Association of Boards of Pharmacy (NABP) that registers pharmacies, part of the registration process now is asking pharmacies if they participate in 340B programs. If a pharmacy attests they participate in 340B, they can see a reduced payment, not only in the drugs identified as 340B, but also for their entire book of business. **Marty Carty** agreed that discrimination is happening.

Chair Akil Patterson thanked OPCA for providing this insight. He said he has been a huge supporter of the 340B program around FQHCs, particularly in marginalized communities, disenfranchised communities, and rural communities. Sometimes FQHCs are the only access to care.

Ralph Magrish said the board has the responsibility to make recommendations to the Legislature each calendar year. Some things the board heard today could potentially shape 340B-specific recommendations.

Fee Structure Rule Discussion: Cortnee Whitlock discussed the draft fee structure rule on Page 21 of the agenda packet. She said this is a work in progress and staff is finalizing the proposed methodology and billing process to present to the board at future meetings. **Shelley Bailey** said she looks forward to hearing stakeholder input during the RAC. She said, when talking about gross revenue, the board wants to make sure, to the extent possible, to include when a manufacturer is selling things at the 340B price or sub 340B price or giving discounts to contract pharmacy partners and payers.

Quarterly Drug List: **Ralph Magrish** said the board's enabling legislation differs from other states that have to construct their own methodology and build a feeder list for affordability reviews. The Oregon Drug Price Transparency program per statute produces these lists for reporting requirements from manufacturers and carriers. Staff is directed to present these lists to the board on a quarterly basis. Feedback will be about the process, not about the drugs per se. He discussed the annual price increase list from Page 22 of the agenda packet. Manufacturers are required annually to submit pricing reports to the Drug Price Transparency. Reports received in 2022 reflect increases of average drug prices 2020-2021. In 2022, the program received 102 annual price increase reports, each one for a different National Drug Code Directory (NDC) designation, from 21 different manufacturers. This is a decrease from 143 reports received in 2021. On the generic side, the program received price increase reports for 22 generic drugs from five manufacturers. Staff also received reports for 27 brand name drugs from 16 manufacturers. Patient assistance programs were reported for 10 of those brand drugs from six manufacturers. The median price increase was 19.9 percent for generic drugs and 13.4 percent for brand drugs.

Robert Judge asked if the board is limited to looking at the DPT price increase drugs or can the board look at drugs for which the state of Oregon spends a large amount of money. Ralph said the board is limited to looking at the DPT list. **Dr. Bruno** asked if it is possible to get a breakdown of dosing formulation these are referring to. **Vice Chair Bailey** asked about quantity. Ralph Magrish said he will ask counsel how much detail can be shared publicly.

Cortnee Whitlock showed Page 23 of the agenda packet, highlighting the top drugs that were injectables versus suppositories. She asked board members if this was a helpful way to break down the information. **Chair Akil Patterson** said yes, it is helpful to organize by administered injectables, an important distinction for someone who has a disease such as Crohn's and physically goes in an office to see a medical professional to get the medication. **Rebecca Spain, Amy Burns, Shelley Bailey** agreed.

Ralph Magrish showed Page 24- 27 for specialty drug reporting requirements. Manufacturers are required to submit a new prescription drug report to DPT within 30 days of introducing a new product with the list price of $670 or more for a 30-day supply or for a course of treatment, shorter than one month. The reporting period on this data was between Oct. 4, 2021, and Aug. 31, 2022. The program received 530 new high-cost drug reports, each one for a different NDC. These reports were submitted by 114 different manufacturers. We received new high cost drug reports for 173 generics from 54 different manufacturers, and also received reports for 84 brand name drugs that came from 66 manufacturers.

Cortnee Whitlock said the lists on Pages 24-27 are divided by drug name and therapy class. She asked if the board members prefer these categories. **Robert Judge** said it is always easier for him to start with a therapy category and then the drugs within the therapeutic category

Ralph Magrish said the lists on Pages 28-31 are from information the health insurance carriers are required to report to DCBS each year as part of the rate filing process. Health insurance companies report lists from their top 25 most prescribed drugs, top 25 drugs with the highest total health plan spending and the top 25 with the greatest increase of year-over-year plan spending. **Cortnee Whitlock** said the COVID-19 vaccination will fall off as new reporting numbers start coming in. She said these lists are examples to show what lists will look like for choosing drugs for the affordability review. **Robert Judge** asked if the year-over-year column is independent of a change in utilization of a drug and reflective of inflation or is there a way to break out use versus inflation? **Ralph Magrish** said the column likely represents the dollars and cents aspect. He said staff could discuss whether there would be data points in the All Payers All Claims database to do analysis about use trends.

Amy Burns recommended flagging drugs that show up on multiple lists with an increase of more than 10 percent or more than $100. It will not tell the whole story but it will tell the utilization numbers that Robert Judge is talking about, she said. **Robert Judge** asked if there is any way to get to net cost in the reporting? **Ralph Magrish** said he suspects the answer is no because the rebate reporting is aggregated by the Drug Price Transparency program. **Robert Judge** said the board may need to call that out to be fully transparent. **Dr. Rebecca Spain** said understanding the utilization increase versus the price increase is important information, particularly if the board recommends fixes. Dr. Burns' suggestion of cross referencing the various pieces of information so they have more context is a great start. If it is going up in price, the board can guesstimate a calculation about utilization. Maybe there is additional information that can give the board that trend over time.

Cortnee Whitlock showed the insulin lists on Pages 32-34 and asked the board if they have preferences on how they would like the data organized or structured in a meaningful way. **Richard Bruno** recommending sorting the three pages of insulin by price to help the board quickly find those with high cost.

Draft Affordability Review: Cortnee Whitlock said board members provided the following feedback and questions about the draft affordability review on Page 35:
* Expand the criteria to include extended pathway approval for orphans, fast track, priority review, accelerated approval, and breakthrough therapy designations.
* Use therapeutic alternatives instead of equivalents.
* Could expenditures include gross per prescription and per course of therapy?
* Is it possible to find the cost of therapy per individual who is using the drug?
* Look at the estimated average monetary price concessions as a percentage.
* Is there information, outside of fee for service, showing how drugs are capturing 340B pricing through the safety net, and how much of that is being passed through to help consumers?
* Look at average patient cost and whether a product is supported by manufacturer assistance or coupons.
Robert Judge said coupons and other patient assistance programs help people afford high-cost medications, but have a bearing on overall costs. It would be helpful to capture coupon information, if possible. **Ralph Magrish** said they would find out if that data is available from OHA. He asked board members to think about a methodology to study drugs with multiple approved indications. **Cortnee Whitlock** said staff will bring a red-line version of the draft affordability review to next month's meeting after the conversation with the RAC.

Public comment: The chair allocated three minutes for public comment. Asher Lisec, regional vice president PhRMA, provided testimony to the board. PhRMA's written comments are posted online: https://dfr.oregon.gov/pdab/Documents/20230315-PDAB-public-comments.pdf

Adjournment: The meeting was adjourned at 11:24 a.m. by Chair Akil Patterson, with a motion by **Amy Burns** and a second by **Richard Bruno**.

Comparative effectiveness: a tool to inform prescription drug affordability

Presentation to the Oregon Prescription Drug Affordability Board

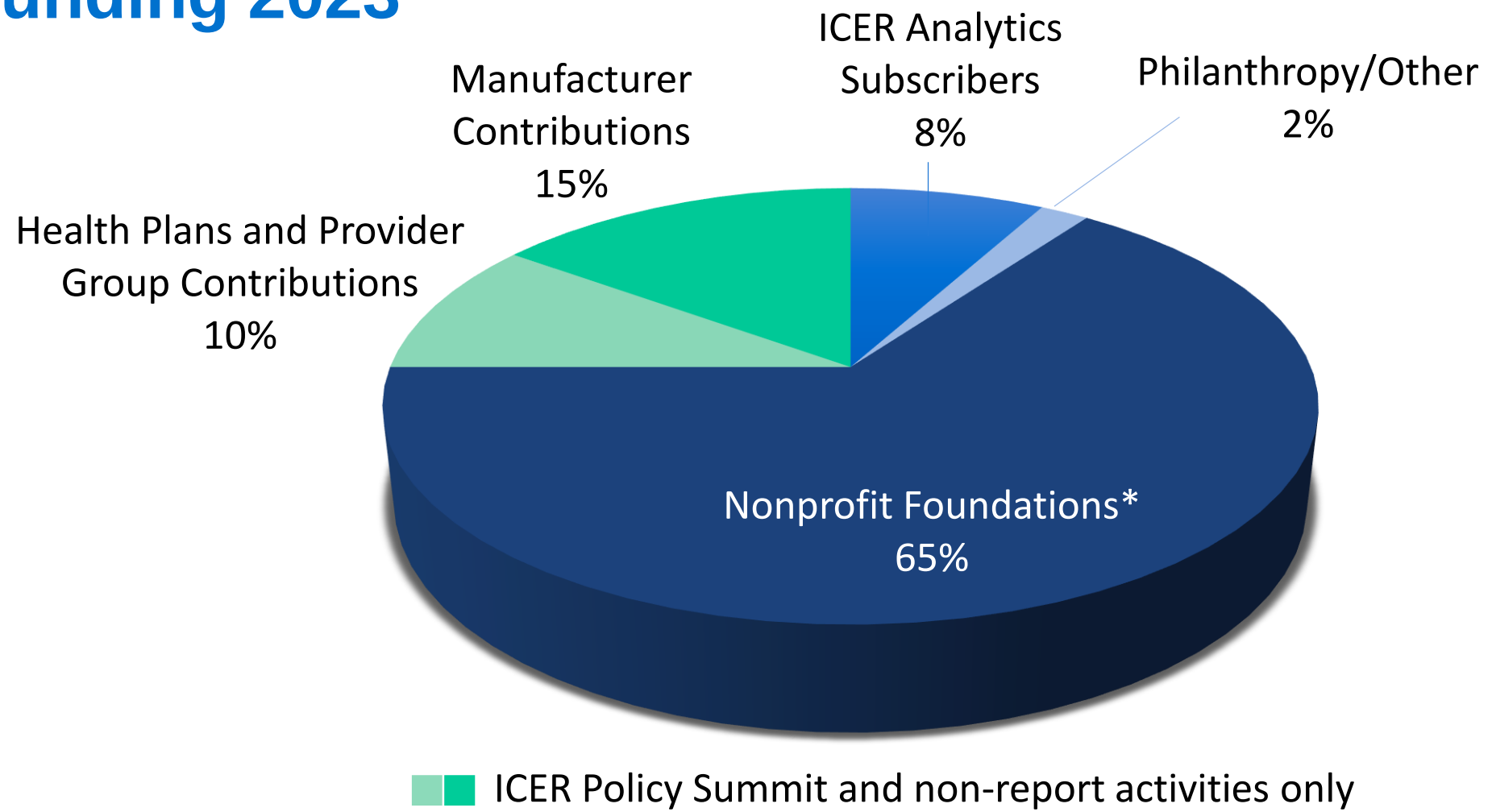
April 19, 2023

ICER
INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW

Institute for Clinical and Economic Review (ICER)

- **Independent, non-partisan** health technology assessment group whose reviews are funded by non-profit foundations
- Develop **publicly-available value assessment reports** on medical tests, treatments, and delivery system innovations for nearly 15 years
- Convene regional independent **appraisal committees** for public hearings on each report
- For some analyses, use cost-effectiveness analysis to determine **health benefit price benchmarks**
- Produce annual list of Unsupported Price Increases using **comparative clinical effectiveness** expertise
- Annual **“Fair Access”** report examining whether insurers are providing fair access to drugs

Funding 2023



https://icer.org/who-we-are/independentfunding/sources-of-funding/

*ICER received significant funding from Arnold Ventures, The California Health Care Foundation, and The Commonwealth Fund

Foundations of our Mission

- Transparent, public, multi-stakeholder approach to all our work
  - Life sciences manufacturers, patient and consumer advocacy organizations, health plans, state and federal policymakers, clinicians, health systems
- Distinctive combination of academic rigor and practical application to support population health
- Guidance to improve the health system so it better serves patients

Fair Pricing.

Fair Access.

Future Innovation.

Value Assessment Framework: What is “Value”?

Comparative clinical effectiveness is the foundation

Patients Engaged in Every Review

- Patient groups notified before review is announced
- Patients and patient groups give input into review scope – population, interventions, comparators, outcomes
- Patient input guides development of other benefits and contextual considerations
- Patients review the preliminary economic model, draft report, draft voting questions
- Patients front and center at entire public meeting, offer public comment, and contribute to the policy roundtable

Public Meetings

- Public deliberation of report contents and policy implications by independent appraisal committees
- Patients and patient organizations play a central role at public meetings
- Participation by clinical experts, manufacturers, patients and caregivers
- The voting panels are comprised of clinicians, patients, and health policy experts

ICER's Value-based Price Benchmarks (Examples)

Assessment	Drugs	Discount Needed*
Spinal Muscular Atrophy	Spinraza	83-90%
Opioid Use Disorder	Probuphine and Vivitrol	53-69%
Rheumatoid Arthritis	Rinvoq	25-26%
Asthma	Xolair, Nucala, Cinqair, Fasenra, Dupixent	62-80%
Treatment-Resistant Depression	Spravato	25-52%

Assessment	Drugs	Discount Needed*
Spinal Muscular Atrophy	Zolgensma	0%
Cardiovascular Disease	Xarelto	0%
Migraine	Nurtec, Ubrelvy	0%
CAR-T for Leukemia and Lymphoma	Yescarta and Kymriah	0%
Hemophilia A	Hemlibra	0%

Commitment to Health Equity

- Recent White Paper highlighting ways our work can address and improve health equity (link below)
- Each ICER report will evaluate clinical trial diversity by comparing trial population to disease-specific prevalence estimates
  - Overall diversity rating for each trial will be provided
- Each ICER report will have a Health Improvement Distribution Index estimating the impact of new treatment on overall health disparities

https://icer.org/assessment/health-technology-assessment-methods-that-support-health-equity-2023/

Protections for patients with disabilities

- Developed in response to and in conjunction with disability community
- Cost-effectiveness approach that values all life extension the same, regardless of disability status = equal value of life years gained (evLYG)
- Offers consistent approach to measuring clinical benefit across drugs and across conditions

Opportunities for PDAB use

- All reports publicly available to offer insight into comparative clinical effectiveness (also access to ICER Analytics™)
  - Reports reflect significant input from many stakeholders including patients
  - Reports will feature measures to address health equity
- Evaluation of fair price by ICER can be one input into deliberations on upper payment limits and affordability
- Scaling prices to benefit patients receive maintains incentives for future innovation
- Important safeguard language exists to ensure non-discriminatory measures are used

Comparative effectiveness: a tool to inform drug price affordability

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April 19, 2023

ICER
INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW

2023 Drug Pricing Legislative Update – PDAB 4/19/23

DCBS-supported legislation

Bill #	Relating Clause	Bill Summary	Status
SB 192	Relating to prescription drugs; prescribing an effective date.	Requires pharmacy benefit managers to annually report to Department of Consumer and Business Services information about certain rebates, fees, price protection payments and other payments received from prescription drug manufacturers.	Alive, in Senate Rules. Passed Senate Health Care Committee 4/3.
SB 404	Relating to prescription drugs; prescribing an effective date.	Requires pharmacy benefit managers and group purchasing organizations to annually report to Department of Consumer and Business Services information relating to prices, rebates, fees and similar information.	Alive, in Joint Ways and Means. Passed Senate Health Care Committee 3/22.

Active external legislation

Bill #	Relating Clause	Bill Summary	Status
HB 2630	Relating to exemption of prescription drug sales; prescribing an effective date.	Exempts receipts from sales of prescription drugs by a pharmacy from commercial activity subject to corporate activity tax.	Alive, in House Revenue. No action to date.
HB 2725	Relating to pharmacy benefit managers; declaring an emergency.	Prohibits pharmacy benefit manager from imposing fees on rural pharmacies after point of sale.	Alive, referred to House Rules from House Behavioral Health & Health Care committee without recommendation.
HB 3012	Relating to pharmacy benefit managers.	Requires pharmacy benefit managers to annually report specified information to Department of Consumer and Business Services, including costs and rebates of prescription drugs for enrollees.	Alive, referred to House Rules from House Behavioral Health & Health Care committee without recommendation.
HB 3013	Relating to pharmacy benefits; declaring an emergency.	Requires pharmacy benefit managers to be licensed by Department of Consumer and Business Services beginning January 1, 2024, and imposes new requirements on pharmacy benefit managers.	Alive, referred to House Rules from House Behavioral Health & Health Care committee without recommendation.

SB 61	Relating to exemption of prescription drug sales; prescribing an effective date.	Exempts receipts from sales of prescription drugs by a pharmacy from commercial activity subject to corporate activity tax.	Alive, in Senate Finance and Revenue. No action to date.
SB 608	Relating to prescription drugs; prescribing an effective date.	Prohibits insurers offering policies or certificates of health insurance and pharmacy benefit managers from requiring claim for reimbursement of prescription drug to include modifier or other indicator that drug is 340B drug.	Alive, passed Senate on 4/12, awaiting action in House.

Dead bills

Bill #	Relating Clause	Bill Summary	Status
HB 2715	Relating to insurance coverage of prescription drugs.	Prohibits health insurers and pharmacy benefit managers from restricting coverage of physician-administered prescription drugs that are obtained by nonparticipating pharmacies.	Dead
HB 2716	Relating to reimbursing the cost of prescription drugs.	Prohibits specified practices by insurers and pharmacy benefit managers in reimbursing cost of prescription drugs.	Dead
HB 2742	Relating to health care costs.	Excludes certain costs from consideration as total health expenditures for purposes of Health Care Cost Growth Target program.	Dead
HB 2762	Relating to prescription drug costs.	Requires insurers offering health benefit plans and pharmacy benefit managers to provide specified information regarding prescribed drug covered by plan or administered by manager, at time drug is prescribed.	Dead
HB 3015	Relating to pharmacy benefit managers.	Prohibits pharmacy benefit manager, after adjudication of and payment on claim for reimbursement of prescription drug, from recouping reimbursement paid except as part of routine audit, or from imposing retroactive fee on basis that was not determined when claim was adjudicated.	Dead
SB 565	Relating to the cost of health care.	Requires insurer, pharmacy benefit manager, Public Employees' Benefit Board, Oregon Educators Benefit Board and health care service contractor to count payments made by or on behalf of enrollee for costs of certain prescription drugs when calculating enrollee's contribution to out-of-pocket maximum, deductible, copayment, coinsurance or other cost-sharing for drugs.	Dead

Rulemaking Advisory Committee (RAC): Affordability Review Rules
Prescription Drug Affordability Board
April 5, 2023, 1:00 -2:33 pm, Summary Notes

Committee members in attendance: Dharia McGrew, Pharmaceutical Research and Manufacturers of America (PhRMA), Kevin Russell, Oregon State Pharmacy Association (OSPA), LuGina Mendez-Harper, Pharmaceutical Care Management Association (PCMA), Maribeth Guarino, Oregon State Public Research Group (OSPIRG), Christine Radkey, Regence Blue Cross Blue Shield - Cambia Health Solutions, Rick Blackwell, PacificSource Health Plans. **Members not in attendance**: Andrea Meyer, AARP, Rocky Dallum, Oregon Bioscience Association. **Interested parties**: Jennifer Olson, Government Relations Strategies, Joe Gardner, PhRMA, MaryAnne Cooper, Cambia Health Solutions. **Staff**: Department of Consumer and Business Services: Cortnee Whitlock, Karen Winkel, Ralph Magrish, Steve Kooyman, Melissa Stiles, Cassie Soucy, Numi Rehfield-Griffith. Department of Justice: Pramela Reddi, Jacob Gill

Cortnee Whitlock, program and policy analyst for the Prescription Drug Affordability Board, thanked everyone attending today's RAC to provide feedback and advice for the development of the draft affordability review rule. The meeting was recorded. The notice for today's RAC was published in the Oregon Bulletin and the PDAB RAC website on March 21, 2023. On March 27 the Rules Coordinator was notified of calendar conflicts with a Senate hearing so the RAC was rescheduled for today. On March 28 the updated agenda was posted to the Oregon Bulletin and the PDAB RAC website. Written comments will be accepted until 5:00 p.m. Pacific Standard Time, April 10, 2023. Please send your comments to Karen Winkel, Division Rules Coordinator at DFR.Rules@dcbs.oregon.gov.

Background and history: The Prescription Drug Affordability Board (PDAB) was enacted as part of Senate Bill 844 (2021) within the Department of Consumer and Business Services with the purpose to protect consumers and other entities from the high cost of prescription drugs. The law provides authority for the PDAB to adopt rules necessary for the administration of the board (ORS 646A.693(18)). The Administrative Procedures Act (the APA) requires state agencies and boards to adopt rules related to the procedure. The Attorney General's Office has provided model rules for agencies and boards to utilize for creating the process to engage in these crucial functions (ORS 183.341). The Attorney General's Office recommends that all agencies and boards adopt the model rules for procedure around rulemaking to comply with the APA. Today's proposed draft rule is for the Affordability Review which the board is required to do to determine prescription drugs affordability. The intention of this rule is to establish the methodology and process for PDAB to annually conduct an affordability review 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.

RAC member feedback:

What are the data sources and what will they be used for?

LuGina Mendez Harper, PCMA, said there is the Oregon Drug Price Transparency (DPT) program, the Prescription Drug Affordability Board (PDAB), and the All Payer All Claims (APAC) data base. Will the PDAB use all of that data reported to DPT and APAC for the criteria in this draft rule? **Cortnee Whitlock** said the Drug Price Transparency program will provide the board with the required data points that are structured under the ORS 646a .689 and ORS743.025. Both of those will feed into this information for

the affordability review. **LuGina Mendez Harper** said there are sections for manufacturer data and information reported by insurers. That information will be shared with the PDAB and the PDAB will also be looking at the All Payer All Claims database for all these criteria, correct? **Ralph Magrish** said the reports from DPT, manufacturer reports and carrier submissions, are feeders to funnel down to a list for applying the criteria to determine the drugs for affordability reviews. All Payer All Claims (APAC) database would not be the data source exclusively. It would be complementary. The agency has authority both through the language in the enabling legislation and through insurance code to make request of carriers for specific information as it relates to net of rebate cost, impact of copays, premiums, those types of data points that are prescriptive in Section 2 of Senate Bill 844. **LuGina Mendez Harper** asked if the data PDAB will be using to conduct these reviews is coming from those sources. **Ralph Magrish** said yes, but with that said, it could be from the Orange Book, different publicly-available data points, or proprietary data that we would have license to use.

Is the rule document a mix of statute and rule? What is the lag time for the data?

Rick Blackwell, PacificSource, asked if they were working off the draft outline received on March 29 and Cortnee said yes. He asked if the draft outline is a mix of the statute and rules that will be adopted. Are we looking at one document that would include both statutory text and rule text? He asked what is the most current data set available from APAC and what is the lag time for the data. He said it seems like it was a couple of years. **Cortnee Whitlock** said there is at least a two-year lag because it has to do with certification of the information. Anything that's presented in 2023 is from 2021. APAC is cited in this document but we're still looking at other sources that meet the need. She said Conducting an Affordability Review, (4) lower case (a) includes everything the statute requires for the board to review. Lower case (b) includes additional components to supplement and support lowercase (a).

Will insulin be removed from the affordability review list?

Christine Radkey, Regence/Cambia, asked about the drugs that will be reviewed and how they will be chosen. Considering the cost of insulin has dropped by Novo and Eli Lilly and Sanofi, will it still be part of the selection of drugs to review? **Cortnee Whitlock** said it will be up to the board members. **Ralph Magrish** said as things stand today, we are bound by statute to implement as written. If two years from now, insulin is affordable for every person in America and it's not on the table, we would seek a legislative fix to remove that and see what more prudent issues to address as a board.

How will the board weigh the criteria?

Christine Radkey asked about the draft outline, if there's a methodology to how things will be chosen. Looking at our own data at Regence, if you were to focus on the most costly drugs, let's say the top nine drugs, most all of those will fall into specialty and would not have a huge impact on the number of patients in the community. Will there be more weight put on the number impacted or price increases year over year? Do you have an idea of how those things will be weighted? **Cortnee Whitlock** said she doesn’t have the answers because the board still is discussing this. She will be taking feedback from the RAC to to the board and is happy to provide that question to the board.

Recommendation to add insurance plans to (J) Input from Specified Stakeholders.

Christine Radkey said she imagines it could get really hard to dial down on what drugs to focus on. Also, as part of Section J Input from Specified Stakeholders, we make a recommendation to add the plans as

part of the stakeholders. We bear the brunt of drug costs. For Regence, we bear about 86 percent of the drug costs, which ultimately impacts affordability for members and the employer groups we serve. If we could be added to the stakeholders, that would be much appreciated. **Cortnee Whitlock** said she will take that to the board to discuss.

Recommendation to include a provision when equivalent generics or biosimilars are not available.

Maribeth Guarino, OSPIRG, asked about the selection of which prescription drugs would go out for the affordability reviews. She noticed there was a provision for when there are therapeutic equivalents for the prescription drug to consider the cost and availability of other equivalents. But she didn't see anything relating to when there were not equivalent generics or biosimilars. She suggested there be a provision to review patents that are pending or patent expirations so we will know when to expect a generic to be available. **Cortnee Whitlock** said that is good suggestion and she will let the board know. **Ralph Magrish** asked RAC members who have language changes or ideas for the rules to please submit in writing by Monday.

Recommendation to include more detail in the metrics and explain how will they be weighted.

Dharia McGrew, PhRMA, said after the board receives the various lists of drugs provided from DCBS from existing reports, there are a lot of metrics listed for analysis of things that could be considered for what would lead to affordability review. We believe these rules need to be far more detailed on where some of these data points are to be found or data will be used. When you're talking about health equity impact, for example, what does that mean? What data will you be looking at and where will you be finding it? What sources will be used? We think that should be explored more and fleshed out more before this is finalized. As was mentioned also, how are you going to rank the different metrics once you have any data that is available if you can achieve it. We really think there needs to be more evaluation of how the board will look at those metrics, how they will weigh those metrics, how they will consider those. We have filed a letter when this was considered at the PDAB. We will also file more comments on that following after this meeting. **Cortnee Whitlock** said she appreciates the feedback and suggestions. **Ralph Magrish** said if Dharia knows of other data sources or has recommendations for inclusions or proposals around Health Equity and other criteria, please submit those as well.

Recommendation to include a definitions section.

LuGina Mendez Harper asked if there will be a section of definitions in the rule. For example, it talks about looking at historical and current pricing data including wholesale acquisition cost and average sales price of a prescription drug. We know what wholesale acquisition cost is, but what is average sales price, how is that defined, where will the board get that information. Generally, we can go to a definition section to find a clearer picture of where this information is coming from. There were a couple of terms used throughout the rule that I wondered, where are they getting that from? So that would be helpful. **Cortnee Whitlock** said she will pass on that suggestion to the board.

Recommendation to restructure the rule format and remove the statutory requirements.

LuGina Mendez Harper followed up on the Rick's question on conducting an affordability review Section (4) little (a). To make sure I understand, little (a) is all of the stuff that's in statute, so there's nothing to be changed in that section or commented on. But in (4) little (b), which is the additional criteria, those are not necessarily stated in statute. So that is where there's an opportunity to provide comment and

feedback on, correct? **Cortnee Whitlock** said that is correct. **LuGina Mendez Harper** asked is (c), (d), and (e) is statutory language and if there is opportunity to comment on those sections. **Cortnee Whitlock** said they can provide comments on c), (d), and (e).

Richard Blackwell said he appreciates Lucina bringing that up because he is struggling with what the division is interpreting through the rulemaking from or clarifying out of SB 844 that's not already there. He would feel a little more comfortable with a more traditional draft rule showing the rules that we need to clarify. The mix of statute and rule is hard to follow and makes it difficult to parse what is already a law and what needs to be clarified in the rulemaking process. **Cortnee Whitlock** said thank you for that suggestion.

Will the rule be made public?

Christine Radkey asked once the draft is finalized, will it be public. **Cortnee Whitlock** said it will be posted with the material packet on the PDAB website prior to the board meeting. Karen Winkel said the draft rules will be public through the Secretary of State website as well.

Is this the same draft the board reviewed on March 15?

Dharia McGrew asked if there we're any changes made from when the board last heard it to this draft. **Cortnee Whitlock** said this is the same presentation that went to the board.

Will the RAC be able to comment on the fiscal impact statement?

Richard Blackwell said on the fiscal statement, will that be something the board will sign off on before filing with the Secretary of State or is that something the RAC would have any input on. **Karen Winkel** said the board will sign off with the RAC input.

What are the next steps?

LuGina Mendez Harper asked what are the next steps? We will provide comments on April 10. Is there another RAC meeting? **Cortnee Whitlock** said they are not planning at this time to do another RAC. Any additional comments can be submitted by 5pm on April 10 or directed to the board through the public comment portion of the board agenda. They can submit written testimony or sign up to provide verbal testimony. All the information presented here will go to the board members for review and implement if they feel it is essential and then they will continue on with the process through the board meetings.

What about the RAC for the fee structure?

Dharia McGrew asked if this meeting was also to discuss the proposed fee structure or just the affordability review. She said the fee structure is on the agenda for the next board meeting. **Cortnee Whitlock** said they will not discuss the fee structure today. The fee structure was pulled due to working on methodology and process. There will be a separate RAC held for that. **Cortnee Whitlock** Thank you asking about that Dharia and bringing it to my attention.

Public Comment: **Karen Winkle** said the public comment portion of the agenda is for non RAC committee members who would like to speak. There were none. **Cortnee Whitlock** thanked everyone for their feedback. She will present all of these suggestions to the board at the next meeting on April 19.

Summary Table

Questions	RAC member	Rule Section
What are the data sources and what will they be used for?	LuGina Mendez Harper, PCMA	(2)
Is the rule document a mix of statute and rule?	Rick Blackwell, PacificSource	(4) (a) (4) (b)
What is the lag time for the data?	Rick Blackwell	(2)
Will insulin be removed from the affordability review list?	Christine Radkey, Regence/Cambia	(2)
How will the board weigh the criteria?	Christine Radkey	(3) (a)
Will the rule be made public?	Christine Radkey	(4) (d)
Is this the same draft the board reviewed March 15?	Dharia McGrew, PhRMA	
Will the RAC be able to comment on the fiscal impact statement?	Rick Blackwell	
What are the next steps?	LuGina Mendez Harper	
What about the RAC for the fee structure?	Dharia McGrew	
Recommendations	**RAC member**	**Rule Section**
1. Include more detail in the metrics. How will they be weighted? What data will be used? * See attached comment	Dharia McGrew, PhRMA Christine Radkey, Regence/Cambia	(4) (b) PDAB conducts an affordability review by considering, to the extent practicable, the additional following criteria:
2. Include definitions	LuGina Mendez-Harper, PCMA	(2) - (4)
3. Include a provision when equivalent generics or biosimilars are not available. * See attached comment	Marybeth Guarino, OSPIRG	(3) (a) Selecting Prescription Drugs for Affordability Review
4. Restructure the format and remove statutory requirements * See attached comment	Rick Blackwell, PacificSource, Marybeth Guarino, OSPIRG	(4) (a) (4) (b)
5. Maintain additional criteria for review * See attached comment	Marybeth Guarino, OSPIRG	(4) (b)
6. Add insurance plans * See attached comment	Christine Radkey, Regence/Cambia	(J) Input from Specified Stakeholders

From: Radkey, Christine <Christine.Valerio@regence.com>
Sent: Wednesday, April 5, 2023 3:21 PM
To: WINKEL Karen J * DCBS <Karen.J.WINKEL@dcbs.oregon.gov>; Cooper, Mary Anne <MaryAnne.Cooper@cambiahealth.com>
Subject: RE: 3/29 RAC for PDAB rulemaking

Hello Karen,

I wanted to provide our feedback in writing for the PDAB rulemaking draft.

Under section 3, we are curious if the selection of drugs will be more heavily weighted on highest cost drugs (i.e. specialty), number of persons impacted (i.e. likely not the most costly drugs on the market but have the broadest impact), or drugs that have the greatest increase in price, year over year. We recognize that sifting through the data and determining the drugs to be reviewed will be complex and that the methodology of weighting each metric may not be defined at this time. Once drugs have been selected and gone through this process, it would be great for PDAB to share at some point, what factors went into selecting a drug for review.

We also want to suggest that plans and payers are added to section I, to provide input as a stakeholder. Our plan's spend on drugs is about $2.7 billion and we bear the majority of these drug costs at about 86%. The increasing costs of drugs have a direct impact on our opportunity to make healthcare affordable. We have a large population in the state of OR and we have a vested interest in mitigating overall affordability for our members and the employer groups we serve.

I've drafted an amendment to section I below:

iii. Payers: "Seek input from health plans, payers and employer groups, managing the cost of the prescription drug that is under review by PDAB, including:

1. Total cost of care for disease(s)
2. Cost of drug to the plan
3. Place in therapy and the availability of therapeutic alternatives on the formulary
4. The management strategies used, driven by the affordability of the drug (i.e. site of care program)
5. Other costs to consider (i.e. cost drivers including hospital up-charges, manufacturer price increases)
6. Coverage mandates and impacts to PMPM and/or premiums
7. Concerns expressed regarding the affordability of the drug under review, from employer groups "

Thank you so much for your time and consideration. Please let me know if there are any questions that I may answer or clarify.

Best regards,

Christine Radkey, PharmD
Clinical Pharmacist Consultant
206-332-4849

April 7, 2023

TO: Rules Coordinator for the Prescription Drug Affordability Board
FR: Maribeth Guarino, OSPIRG & OCAP
RE: PDAB rules for selecting drugs to review

OSPIRG is a public interest organization with members across the state. We advocate for policies to lower the cost of health care and make our world a healthier, safer place. The Oregon Coalition for Affordable Prescriptions (OCAP), is a diverse coalition of organizations and advocates that work to rein in drug prices and hold the pharmaceutical industry accountable. Both OSPIRG and OCAP have worked to lower the cost of prescription drugs for Oregonians, including supporting SB 844, the bill that created this board in the 2021 legislative session, and we appreciate the opportunity to provide feedback on the PDAB's affordability review rules. While the rules are mostly consistent with the statute and in line with the goals of the PDAB, we have a few comments.

Include consideration of patents in determining availability of equivalent drugs
Section 3(a) provides that the PDAB will consider the availability of generics, biosimilars, and therapeutic equivalents, as well as their cost. However, there is no specific consideration for brand-names without a generic alternative. We recommend adding a subsection (d) that provides:

> "Where there is no therapeutic equivalent, PDAB may consider the expected patent expiration for the drug and when a therapeutic equivalent could become available, including the number of patents approved or pending for a drug that may delay a generic from being developed or entering the market."

The additional consideration for prescriptions where a single drug is the only choice available to consumers due to patent law and other market considerations is a vital aspect of understanding and lowering the cost of prescription drugs for Oregonians.

Keep the rule to rulemaking
To the extent that the current draft solely reiterates the statute, we agree with statements made during the RAC hearing that repeating the law itself creates confusion in the rulemaking process. We recommend deleting that language from the rule and using a reference to the statute instead. For example, delete section 4(a) and instead revise section 4(b) to state "In addition to the criteria laid out in ORS 646A.694, PDAB will conduct an affordability review by considering, to the extent practicable, the additional following criteria". This will clarify the rulemaking process and the additional proposed criteria.

Maintain the additional criteria for reviews
The criteria laid out in section 4(b), particularly around the cost to the consumer, co-pays, deductibles, etc. are important. We support the criteria as stated in the rules. We also recommend adding language which allows PDAB to consider a monopoly on a drug or a lack of generic alternatives, as well as any price increases over its time on the market. Without competition on the market, monopolies may lead to unaffordable price hikes which would be important information for the board to consider in its review.

Oregon Prescription Drug
Affordability Board

Prescription Drug Affordability Board

Affordability review draft outline

Cortnee Whitlock
Board Policy Analyst

Selecting prescription drugs for affordability review

1. RAC questions (3)(a)

2. RAC feedback (2) or (3)

(3)(a)Prescription drugs selection:

A. Determine if any prescription medications are on each of the insurer reported top 25 lists.

B. Determine which drugs from the manufacturer reports need to be reviewed.

i. Determine date of FDA approval and whether the drug was approved through an expedited pathway. Expedited approval includes orphan, fast track, priority review, accelerated approval, breakthrough therapy designation.

ii. Determine if drugs are included in the manufacturer launch price or price increase reports for the same calendar year.

C. All insulin drugs marked in the U.S. and available in Oregon are subject to identification for an affordability review.

i. Criteria for identification may include, but not limited to, those products with the highest carrier reported;

1. Overall spend
2. Per patient spend
3. Patient out-of-pocket cost

ii. Historical pricing information relating to;

1. Price increases (percentage and gross)
2. Manufacturer information submitted to the Drug Price Transparency program under ORS 646A.689

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Selecting prescription drugs for affordability review

3. RAC feedback (3)(a)E.

(3)(a)Prescription drugs selection:

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

E. Where there are therapeutic alternatives, PDAB may consider the cost and availability of potential alternatives by evaluating utilization data and spending data.

F. **Option 1:** Eliminate any that are also on the CMS Medicare negation list. **Option 2:** have the following language: prescription drugs on the CMS Medicare negotiation list during a specified period.

G. **Option 1:** Eliminate any that are on the FDA shortage list. **Option 2:** have the following language: prescription drugs on the FDA shortage list.

H. **Option 1:** Identify any prescription drugs having a patent expiration data exclusivity expiration in the next three years. **Option 2:** have the following language: prescription drugs that have a patent expiration data exclusivity expiration in the next three years.

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Selecting prescription drugs for affordability review

~~**(3)(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 publicly available data sources. Expenditures can include gross, per prescription and per course of therapy (monthly, yearly) adjustments;~~

~~D. Utilization associated with the prescription drug, including utilization identified in 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.~~

In order to understand the affordability challenge, should we also understand whether a product is supported by manufacturer assistance or coupons.

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Conducting an Affordability Review

4. RAC feedback (4)(a)

(4) Conducting and 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.

Would it be more correct to have it expressed as a percentage of the amount paid for a drug, including rebates and coupon (assistance programs)?

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Conducting an Affordability Review

(4)(a)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 net price for therapeutic alternatives to the drug

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

I think this should also consider what manufacturers contribute to net cost through PAPs and coupons.

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

Is the intent here to understand off label use? This information is not easily captured and is virtually unavailable via retail claim processing.

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Conducting an Affordability Review

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

What is the intent here? Formulary selection and placement is specific to each payer's plan design and the concessions manufacturers make available for clinically-equivalent therapies.

J. The relative financial impacts to health, medical, or social services costs and 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 the manufacture chooses to provide.

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Conducting an Affordability Review

5. RAC feedback (4)(b)

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

While there is documented evidence supporting pharmacy accessibility as a contributor to underuse of prescription medications, how would we approach this particular investigation?

A. Whether the pricing of the prescription drug results in or has contributed to health inequities in under resourced communities and pharmacy deserts.

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. 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

Could expenditures include gross per prescription and per course of therapy?

E. Potential market for prescription drug for labeled indications and budget impact on various payors in the state

F. 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.

Can we understand what this is? Is it related to underserved communities?

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Conducting an Affordability Review

(4)(b)G. In addition to the criteria in subparagraph (a)(J): relative financial effects of the prescription drug on health, medical, or social services costs.

Is it possible to find the cost of therapy per individual who is using the drug?

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.

Are we allowed to consider other metrics that reflect value such as $ per life year (or equivalent life year)?

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Conducting an Affordability Review

(4)(b)H. 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 publicly available and contracted data sources, including:

i. Copayment;
ii. Coinsurance;
iii. Deductible; and/or
iv. Any other copayment and cost sharing data.

This information is important but does not exist in the data. Plans are unlikely to disclose copay/coinsurance amounts other than in aggregate, if at all, since it can reveal confidential information.

Additionally, while there is no vehicle for collecting this information today, as a methodology, this item should also include patient assistance and copay coupons.

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Conducting an Affordability Review

(4)(b)I. Impact on Safety Net Providers: When the prescription drug is available through section 340B of the federal Public Health Service Act

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.

Is there information, outside of fee for service, showing how drugs are capturing 340B pricing through the safety net, and how much of that is being passed through to help consumers?

This could be informative information to collect but may not be directly helpful to the affordability question. I think this may require discussion. Participation of safety net providers in the 340B program can be implemented in a couple of ways. How safety-net organizations apply their 340B programs could be instructive to learning how this program is assisting to address the affordability question: (1) as a program that provides 340B priced medication to its underserved population; or (2) as a program that generates spread pricing on the 340B product based on what a safety net can be reimbursed for a drug dispensed to an insured member. Care must be taken not to assume that a safety net's access to a drug dispensed with a 340B purchase price is targeted at assisting those with prescription drug affordability challenges.

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Conducting an Affordability Review

(4)(b)J. Input from specified stakeholders

I understand it is critical to solicit input from patients and caregivers in learning about affordability challenges to prescription drugs. I think this section must also solicit this same input from payers responsible for the overwhelming cost of the drug relative to other options. Without doing so, we are only seeking input from 2 of the 3 parties engaged in this element of the prescription drug affordability question – access is also a formulary discussion.

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) Impact of the disease,
   b) Patient treatment preferences,
   c) Patient perspective on the benefits and disadvantages of using the drug,
   d) Caregiver perspective,
   e) Available patient assistance in purchasing the drug.

I am unsure what this is specifically referring to.

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Conducting an Affordability Review

6. RAC feedback (4)(b)J.iii.

(4)(b)J.(i)2. In seeking additional information, attempt to gather a diversity of experience among patients from different socioeconomic backgrounds.

This should include pharmacists who are specialized in understanding how drugs are used to treat specific conditions and who are close to the question of cost vs. benefit of therapeutic options.

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. 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.

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Conducting an Affordability Review

UM limitations can be driven by P&T decisions after reviewing the clinical literature or by manufacturers given the rebate bids that are proposed to payers. The use of a UM in and of itself is not a non-adherence item. UM is intended to maximize therapeutic efficacy, while ensuring patient safety and the use of cost-effective medicines.

(4)(b)K. Rebates, Discounts, and Price Concessions:

This supports comments in 4(a)(G) above.

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.

L. Information from the Oregon Health Authority, Health Evidence Review Commission, and Pharmacy and Therapeutics Committee:

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

M. 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.

N. 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.

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Conducting an Affordability Review

(4)(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.

Should there be discussion about criteria for assessing a product's afford-ability? Affordability can be challenging because of high net acquisition cost, or because the volume of prescriptions multiplied cost poses affordability questions.

(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.

Recommend using acquisition cost on the buy side, manufacturer to wholesaler to pharmacy, and on the pay side, carrier to PBM to pharmacy to manufacturer rebate.

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Conducting an Affordability Review

(4)(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).~~

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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) Prescription drugs selection:

(A) Determine if any prescription medications are on each of the insurer reported top 25 lists;

(B) Determine which drugs from the manufacturer reports need to be reviewed

i. Determine the date of FDA approval of the eligible prescription drug and whether the prescription drug was approved through an expedited pathway. Expedited approval includes orphan, fast track, Priority Review, Accelerated Approval, and Breakthrough Therapy designation

ii. Determine if drugs are included in the manufacturer launch price or price increase reports for the same calendar year

(C) All insulin drugs marked in the U.S. and available in Oregon are subject to identification for an affordability review.

i. Criteria for identification may include, but not limited to, those products with the highest carrier reported:

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1. Overall spend;
2. Per-patient spend;
3. Patient out-of-pocket cost;

ii. Historical pricing information relating to:

1. Price increases (percentage and gross);
2. Manufacturer information submitted to the Drug Price Transparency Program under ORS 646A.689.

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

(E) Where there are therapeutic alternatives, PDAB may consider the cost and availability of potential alternatives by evaluating utilization data and spending data.

(F) Option 1: Eliminate any that are also on the CMS Medicare negotiation list.
Option 2: have following language: Prescription drugs on the CMS Medicare negotiation list during a specified period

(G) Option 1: Eliminate any that are on the FDA shortage list.

Option 2: have following language Prescription drugs on the FDA shortage list

(H) Option 1: Identify any prescription drugs having a patent expiry/data exclusivity expiry in the next 3 years.

Option 2: have the following language: Prescription drugs that have a patent expiry/data exclusivity expiry in the next 3 years.

(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;

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Deleted: <#>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¶

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<#>¶
<#>Health equity impact, including whether the prescription drug is utilized to treat a condition disproportionately experienced by priority populations;¶
<#>Historical and current pricing data, including wholesale acquisition cost and average sales price of the prescription drug;¶ ...

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(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 NET 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.

Commented [RJ2]: Would it be more correct to have it expressed as a percentage of the amount paid for a drug, including rebates and coupon (assistance programs)?

Commented [RJ3]: The estimated NET price...?

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Commented [RJ4]: I think this should also consider what manufacturers contribute to net cost through PAPS and coupons

Commented [RJ5]: Is the intent here to understand off label use? This information is not easily captured and is virtually unavailable via retail claim processing

Commented [RJ6]: What is the intent here? Formulary selection and placement is specific to each payer's plan design and the concessions manufacturers make available for clinically equivalent therapies.

Commented [RMJ7]: Question: while there is documented evidence supporting pharmacy accessibility as a contributor to underuse of prescription medications, how would we approach this particular investigation?

(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) Potential market for prescription drug for labeled indications and budget impact on various payors in the state.

(F) 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.

(G) 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.

(H) 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 publicly available and contracted data sources, including:

i. Copayment;
ii. Coinsurance;

iii. Deductible; and/or

iv. Any other copayment and cost sharing data.

(I) 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

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Commented [RMJ8]: Can we understand what this is? Is it related to underserved communities?

Commented [DH9]: Are we allowed to consider other metrics that reflect value -- ie $per life year (or equivalent life year)?

Commented [RMJ10]: This information is important but does not exist in APAC. Plans are unlikely to disclose copay/coinsurance amounts other than in aggregate, if at all, since it can disclose confidential information

Additionally, while there is no vehicle for collecting this information today, as a methodology, this item should also include patient assistance and copay coupons.

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Commented [RMJ11]: This could be informative information to collect but may not be directly helpful to the affordability question. I think this may require discussion.

Participation of safety net providers in the 340B program can be implemented in a couple of ways. How safety-net organizations apply their 340B programs could be instructive to learning how this program is assisting to address the affordability question: (1) as a program that provides 340B priced medication to its underserved population; or (2) as a program that generates spread pricing on the 340B product based on what a safety net can be reimbursed for a drug dispensed to an insured member.

Care must be taken not to assume that a safety-net's access to a drug dispensed with a 340B purchase price is targeted at assisting those with prescription drug affordability challenges.

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.

(J) 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,

Commented [RMJ12]: I understand that it is critical to solicit input from patients and caregivers in learning about affordability challenges to prescription drugs. I think this section must also solicit this same input from payers responsible for the overwhelming cost of the drug relative to other options. Without doing so, we are only seeking input from 2 of the 3 parties engaged in this element of the prescription drug affordability question is access is also a formulary discussion.

Commented [RMJ13]: I am unsure what this is trying to understand?

Commented [RMJ14]: This should include pharmacists who are specialized in understanding how drugs are used to treat specific conditions and who are close to the question of cost vs benefit of therapeutic options.

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.

(K) 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.

(L) 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.

(M) 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.

(N) 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

Commented [RMJ15]: This supports comments in 4(a)(G) above.

Commented [RMJ16]: UM limitations can be driven by P&T decisions after reviewing the clinical literature or by manufacturers given the rebate bids that are proposed to payers. The use of a UM in and of itself is not a non-adherence item. UM is intended to maximize therapeutic efficacy, while ensuring patient safety and the use of cost-effective medicines.

Commented [RMJ17]: Recommend acquisition cost on the buy side manufacturer to wholesaler to pharmacy) as well as on the pay (carrier to PBM to Pharmacy to Manufacturer rebate)

Commented [RMJ18]: Should there be some discussion about criteria used for assessing a product's affordability? Affordability can be challenging because of its high net acquisition cost, or because the volume of prescriptions multiplied by its cost poses affordability questions.

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.

Deleted: 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).

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Generic Drug Report 2023

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Acknowledgements

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Introduction

The Oregon Legislature created the Prescription Drug Affordability Board in 2021. One part of the Board's remit is to conduct a study on the operation of the U.S. generic and biosimilar drug markets which includes drugs dispensed by pharmacists and drugs administered by physicians. The board presented its original report in December 2022. The 2022 report provided background on both generic and biosimilar products, markets, and licensing processes.[1] This 2023 report updates the initial work with more detail on generic and biosimilar market trends and builds on the foundational information provided in 2022.

Generic drug products

Quick statistics

- Generics represent 91 percent of all prescriptions in the U.S. but just 18.2 percent of total drug spending[2]
- Generics account for only 3 percent of total U.S. healthcare spending[3]
- Generics saved $338 billion in 2021 in the U.S.[4]
- Biosimilars saved $7 billion in 2021 in the U.S.[5]

Description and nomenclature

Generics are small-molecule drugs synthesized through chemical process and marketed once the patent has expired on the original, innovator branded product. These are tablets, capsules, oral liquids, and other self-administered formulations. As a group, they are referred to as multisource generics or multisource products if there is more than one manufacturer of the generic product.

In general, the innovator product does not engage in price competition with multisource products. Innovator sales drop dramatically once the patent expires and generic equivalents enter the market.

2022 Generic approvals

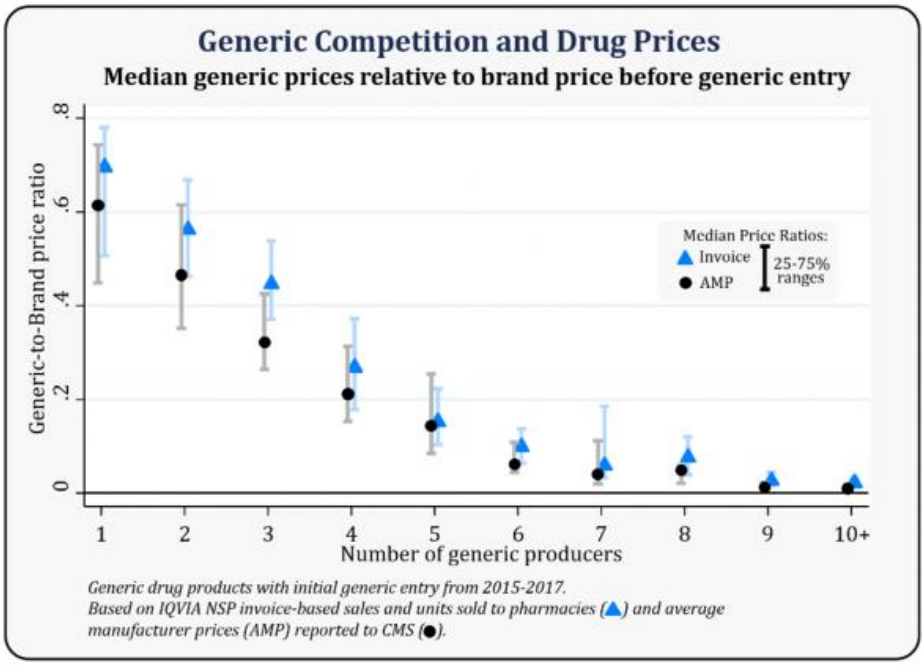
The Food and Drug Administration (FDA) approved or tentatively approved more than 900 generic products in 2022. Some 106 of these were first generics, the first generic on the market after the innovator patent expiration. First generics are allowed 180 days of exclusive market

[1] "2022 Report for the Oregon Legislature: Prescription Drug Distribution System and Generic Drug Reports Pursuant to Senate Bill 844 (2021)." Prescription Drug Affordability Board, Dec. 19, 2022. https://dfr.oregon.gov/pdab/Documents/reports/PDAB-Report-2022.pdf. Accessed April 10, 2023.
[2] Ibid.
[3] Ibid.
[4] Ibid.
[5] "U.S. Generic and Biosimilar Medicines Savings Report: Generics and biosimilar medicines deliver more savings every year." Association for Accessible Medicines, September 2022. https://accessiblemeds.org/resources/blog/2022-savings-report. Accessed April 10, 2023.

access. No other generic can enter the market during that time period. The FDA initiative to encourage more generic products and market competition seems to be bearing fruit. The initiative encourages manufacturers to apply for licenses for products without generic competition. Along with streamlining initiatives, FDA also works more closely with applicants during the licensing process to minimize the extent to which applications have to be returned to the applicant for corrections.

Generic drug market trends and issues

The first generic generally does not provide much price relief because it can shadow the price of the innovator. Studies have shown that first generics might provide up to 30 percent price reduction relative to the brand– which is some price relief for consumers but not the full potential. If there is a fifth manufacturer of the product, the savings can reach 85 percent of the innovator price.



How Generic Competition Helps Bring Down Drug Prices.[6]

Drug shortages

The products on the FDA national shortage list are typically low-cost generics used by hospitals. In response, a consortium of hospital systems created an organization to secure, distribute, and eventually manufacture generic drugs. Using lower-cost generics helps health system control costs.

[6] "How Generic Competition Helps Bring Down Drug Prices." U.S. Food and Drug Administration, Sept. 12, 2022. https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices. Accessed April 10, 2023.

Even though the nation relies on generics for the majority of medication needs, it is not always a stable market for consumers or providers. The downside to multisource competition is that prices can go so low that some manufacturers may decide to exit the market for the product. At a minimum, this allows manufacturers who remain in the market to raise prices and stabilize the market. At worst, stiff price competition and manufacturer exits can lead to drug shortages because there is not enough remaining production capacity to meet demand, at least in the short term until remaining manufacturers can increase production. Drugs shortages have become such a significant issue that the Food and Drug Administration now tracks drug shortages and asks manufacturers for advance warning of material changes to their market participation that could produce a shortage.[7]

Other than a manufacturer exiting the product market, there are other circumstances that could produce a shortage. If a factory goes offline to update manufacturing processes or resolve quality problems there could be supply shortage. Environmental disasters can force manufacturing stoppage due to facility damage, loss of power, or lack of staffing. Environmental disasters could affect wholesaler storage facilities. Ingredient shortages could occur for a number of different reasons which could affect all manufacturers of a product.

Price fixing litigation

The opposite of stiff market price competition is price fixing. A lawsuit by the majority of states was filed in 2016.[8] Another lawsuit was filed in 2020 on behalf of 46 states and territories against 26 manufacturers.[9] States make the case that 1,200 drugs had increased in price an average of 450 percent in one year while some of the products increased up to 1,000 percent. The U.S. Department of Justice has charged seven generic companies with collusion and price fixing. Each case involves a different number of drugs, up to 1,200 generic products.[10] Some of the companies have also faced shareholder lawsuits based on the price fixing charges. A few of the companies have made financial settlements in one or more of the lawsuits.[11]

[7] "Drug Shortages." U.S. Food and Drug Administration, April 5, 2023. https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages. Accessed April 10, 2023.

[8] "Current Cases: Generic Drugs Price Fixing Litigation(filed 2016)." Washington State Office of the Attorney General. https://www.atg.wa.gov/antitrust-cases#generic%20drugs. Accessed April 12, 2023.

[9] Bartz, Diane and Stempel, Jonathan. "U.S. states accuse 26 drugmakers of generic drug price fixing in sweeping lawsuit." Reuters, June 10, 2020. https://www.reuters.com/article/us-usa-drugs-antitrust-lawsuit-idUSKBN23H2TR. Accessed April 12, 2023.

[10] "Generic Drugs Investigation Targets Anticompetitive Schemes. Division update Spring 2021." The United States Department of Justice, March 24, 2021. https://www.justice.gov/atr/division-operations/division-update-spring-2021/generic-drugs-investigation-targets-anticompetitive-schemes. Accessed April 12, 2023.

[11] "Pharmaceutical Companies Pay Over $400 Million to Resolve Alleged False Claims Act Liability for Price-Fixing of Generic Drugs." The United States Department of Justice, Oct. 1, 2021. https://www.justice.gov/opa/pr/pharmaceutical-companies-pay-over-400-million-resolve-alleged-false-claims-act-liability. Accessed April 12, 2023.

Pay for delay

Generic manufacturers sometimes have financial incentive not to enter a market. Pay-for-delay agreements between generic and patent-holding pharmaceutical manufacturers prevent lower-priced generics from entering the market. These agreements tend to eliminate the 180-day period of exclusive market access for the first generic to market. According to the Federal Trade Commission, prescription drug pay-for-delay agreements cost consumers $3.5 billion every year.[12]

U.S. Supreme Court in 2013 found these agreements to be legal within reason.[13] The deals cannot be large and unjustified. The Federal Trade Commission monitors these agreements and has reported that the number of agreements has declined slightly since the Supreme Court decision.

Only California has enacted a law penalizing prescription drug pay for delay agreements.[14] An industry legal challenge succeeded in rolling back the scope and application of the state law but state authority to pursue certain pay for delay deals was maintained.

Generics and pharmacy benefit manager spread pricing

The unethical practice of spread pricing by pharmacy benefit managers (PBMs) typically involves generic drugs. The practice occurs when the PBM reimburses a pharmacy the cost of the dispensed drug, typically using a national average price to set the reimbursement. The PBM then bills the health plan for the drug at a much higher price, possibly even the brand product price. The Centene Corporation, which dominates as the PBM for Medicaid programs, has become quite well known for its use of spread pricing in unwitting Medicaid programs.[15] It has been or is being investigated in 20 states and already settled with 14, including Oregon in December 2022. As a general matter, the Federal Trade Commission decided in 2022 to study PBM business practices because of concern for anti-competitive and other unfair trade practices.

Generic coverage and PBMs

Generic drug availability on health plan formularies can be impeded by brand drug patient assistance programs and rebates. Manufacturers of high-cost brand drugs may offer significant patient cost sharing assistance to greatly reduce the cost of otherwise very costly patient coinsurance. Doctors may prescribe the high-cost patented product rather than an alternative

[12] "Pay-for-Delay: When Drug Companies Agree Not to Compete. Federal Trade Commission." https://www.ftc.gov/news-events/topics/competition-enforcement/pay-delay. Accessed April 10, 2023.
[13] Paradise, Jordan. "The Status of California's Pay-for-Delay Legislation & Litigation." Food and Drug Law Institute. Fall 2022. https://www.fdli.org/2022/08/the-status-of-californias-pay-for-delay-legislation-litigation/. Accessed April 10, 2023.
[14] Ibid.
[15] "Centene Gives Big as It Courts Contracts and Settles Accusations of Overbilling." California Healthline, Dec. 15, 2022. https://californiahealthline.org/multimedia/centene-gives-big-as-it-courts-contracts-and-settles-accusations-of-overbilling/. Accessed April 12, 2023.

generic treatment because the patient cost sharing is less. Similarly, branded manufacturers may offer hefty rebates that bring the PBM net cost of the brand to less than the cost of the generic. Consumers, however, pay cost sharing based on the market price of the drug, not the insurer/PBM net cost. This phenomenon can be taken to extremes, as in the 2022 CVS Caremark scandal.[16]

Generic market disrupters

Drug price increases have affected the generic market to extents similar to the patented market. But unlike the patent-protected brand market, there is more opportunity for market disrupters to operate in the generic market. This is because generic drugs are not patent protected, one manufacturer does not control the price or supply.

Civica and CivicaScript: Civica began in 2018 as a consortium of hospital systems that provided capital for the manufacture of generics important to inpatient hospital care -- drugs that are often in supply shortage and subject to price hikes. The organization has contracted for the manufacture of generic drugs but is now close to opening its own manufacturing plant in Virginia.

Two years ago, CivicaScript partnered with the Blue Cross Blue Shield Association and 18 of its health plans to supply generics at low cost to participating pharmacies and funding members.[17] Other health plans have subsequently joined. The first product of the initiative was a prostate cancer product. Civica recently announced it will begin manufacturing off-patent, long-acting insulins.[18] The products will be available to anyone. Civica will distribute the insulins through every distribution channel but dispensing pharmacies must agree to limit charges to $30 per vial or $55 per pen. Health plans will direct their enrollees to participating pharmacies. Since Civica made this announcement, the three big brand insulin makers announced steep reductions in the price of their insulins.[19]

Cost Plus Drugs: This company started in early 2022 as an online generic pharmacy with 350 generic drugs available. It began as a cash-only business that did not interact with health plans or PBMs. It charges product cost, delivery, and 15 percent mark-up. It has moved quickly to expand its business model. In late 2022, Cost Plus announced it will work with a coalition of

[16] Silverman, Ed. "A veritable playground: CVS whistleblower details how patients were charged higher drug prices." Stat, June 16, 2022. https://www.statnews.com/pharmalot/2022/06/16/cvs-whistleblower-silverscript-medicare-generics/. Accessed April 11, 2023.

[17] Silverman, Ed. "Civica Rx teams with Blue Cross Blue Shield to widen its alternative market for generics." Stat, Jan. 23, 2020. https://www.statnews.com/pharmalot/2020/01/23/civica-blue-cross-shield-generics-drug-prices/. Accessed April 11, 2023.

[18] Civica, 2023. https://civicarx.org/. Accessed April 12, 2023.

[19] Smith, Bram Sable and Young, Samantha. "Eli Lilly Slashed Insulin Prices. This Starts a Race to the Bottom." Kaiser Health News, March 2, 2023. https://kffhealthnews.org/news/article/eli-lilly-slashed-insulin-prices-this-starts-a-race-to-the-bottom/. Accessed April 12, 2023.

public and private employers who will connect their enrollees to Cost Plus generics.[20] To do this, the coalition created their own pharmacy benefit manager paid based on a straight fee for paid claim, which was $3 at the time of the announcement. This in itself is a market disruption. In March 2023, Cost Plus announced a contract with brand manufacturer Janssen to sell their patented anti-diabetic product Invokana for $294 per month, less than half the average retail price of $676 per month. The company now carries 1100 drugs and will add a brand from IBSA Pharma.[21] Cost Plus is also working with independent and chain pharmacies across the country to expand access.

State drug manufacturing initiatives: California and Washington have enacted laws that require the state to either manufacture or contract for distribution of affordable generic drugs. California recently signed a contract with Civica to manufacture insulins that will be available to cash-paying customers.[22] The manufacturing facility is expected to be location in California. Arizona, Illinois, Massachusetts, and New York all have proposed legislation that would follow the lead of California and Washington.

Generic multisource drugs and Medicaid

The Medicaid Drug Rebate Program (MDRP) began in 1990 and applies to branded drugs and generics. A generic manufacturer must provide to each state a 13 percent rebate for each of its products used in the state's Medicaid program, which is calculated for each calendar quarter. If the product price rose faster than the rate of inflation, a manufacturer must pay an additional inflation penalty rebate for each unit of product dispensed in a state's Medicaid program. For years it has been suggested that Medicaid fee-for-service pharmacy benefit programs favored the use of more expensive innovator brands rather than the generic versions because of the larger rebates of the brand products. New York specifically requires coverage of the brand if the net is less costly than the generic.[23]

Oregon and generics

- Oregonians saved $3.6 billion in 2021 on generics and biosimilars according to the generic and biosimilar trade association, Association for Accessible Medicines.[24]

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[20] Silverman, Ed. "True disruption: Mark Cuban's company will sell brand-name diabetes medicines from J&J." Stat, April 4, 2023. https://www.statnews.com/pharmalot/2023/04/04/janssen-diabetes-invokana-cuban-cost/. Accessed April 12, 2023.

[21] Emerson, Jakob and Twenter, Paige. "Leadership & Management: 10 exclusives Mark Cuban told Becker's in April." Becker's Hospital Review, April 11, 2023. https://www.beckershospitalreview.com/hospital-management-administration/10-exclusives-mark-cuban-told-beckers-in-april.html. Accessed April 12, 2023.

[22] "Governor Newsom announces $30 insulin through CalRX." Office of Governor Cavin Newsom, March 18, 2023. https://www.gov.ca.gov/2023/03/18/governor-newsom-announces-30-insulin-through-calrx/. Accessed April 12, 2023.

[23] "NYRx, the Medicaid Pharmacy Program." Magellan Medicaid Administration. https://newyork.fhsc.com/providers/bltgp_about.asp. Accessed April 11, 2023.

[24] "Generic and Biosimilar Medicines Save Oregon Patients Billions." Biosimilars Council, a division of Association for Accessible Medicines. https://accessiblemeds.org/sites/default/files/2023-01/AAM-2022-generic-biosimilar-savings-Oregon.pdf. Accessed April 11, 2023.

- The AAM also finds that the average Oregon Medicare enrollee saved $1,742 in 2021 and total Medicare savings in Oregon due to generics and biosimilars was $951 million in 2021. This is a savings for employer retiree health benefits programs, including state and local government retirees.[25]
- In 2021, Oregon Medicaid spent $778 million on prescription drugs, 81 percent was spent on brands and 18.6 percent on generics, excluding biosimilars, which are technically patented brands. The fee-for-service program spent $135.5 million total and the Medicaid ACO program spent $624.5 million.[26]
- There were 10,190 Medicaid prescriptions filled in 2021. Thirteen percent were filled with brands and 87 percent were filled with generics. Interestingly, 6 percent of prescriptions were for brands in fee-for-service while 15 percent were for brands in the ACO programs. Without looking at the claims, it is impossible to tell what this means.[27]

Biologic and biosimilars

Description and nomenclature

The original/first innovator biologic is called a reference product in the context of a discussion of biosimilars. Biosimilars are a category of biologics. Like all biologics, they are patent-protected, branded products.

- FDA defines a biosimilar as a biologic that is highly similar to, and has no clinically meaningful differences from, the FDA approved reference biologic. This means biosimilars:[28]
    - Are given the same way (same route of administration).
    - Have the same strength and dosage form.
    - Have the same potential side effects.

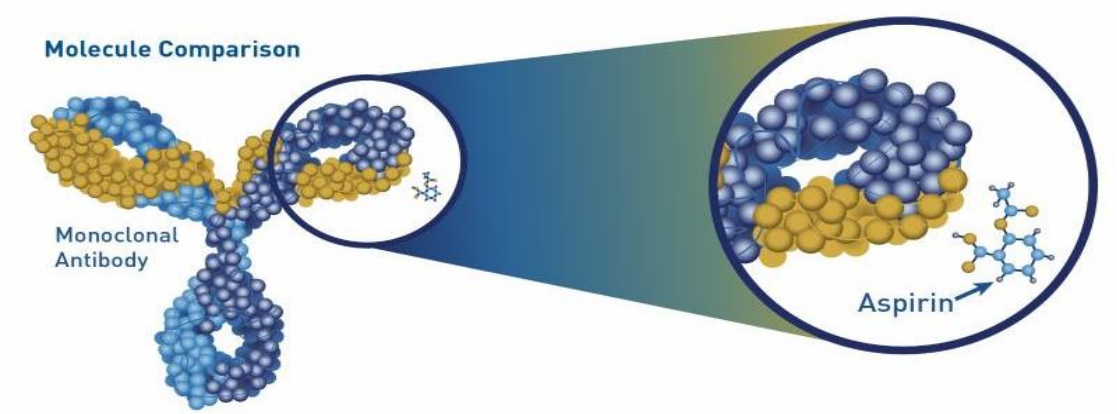
Small molecule generics must be chemically identical within a tight range specified by the FDA. This tight standard is not possible with biologics because biologics are derived from living systems, such as bacteria, yeasts, and other cells. Living cells are not identical, unlike the chemical components of small molecule products. A biosimilar cannot be identical to the reference product but is similar and can be expected to produce the same clinical results.

Biologics are made of large molecules, as opposed to small molecule drugs and their generics. The manufacturing process is complex. Some biologics such as insulin can be self-administered,

[25] "Generic and Biosimilar Medicines Save Oregon Patients Billions." Biosimilars Council, a division of Association for Accessible Medicines. https://accessiblemeds.org/sites/default/files/2023-01/AAM-2022-generic-biosimilar-savings-Oregon.pdf. Accessed April 11, 2023.
[26] Ibid.
[27] Ibid.
[28] "Biosimilar and Interchangeable Biologics: More Treatment Choices." U.S. Food & Drug Administration, Oct. 12, 2021. https://www.fda.gov/consumers/consumer-updates/biosimilar-and-interchangeable-biologics-more-treatment-choices. Accessed April 11, 2023.

but many biologic treatments are administered in outpatient clinic or inpatient settings. Congress created a new, separate approval pathway for biologic/biosimilars in the 2009 Biologics Price Competition and Innovation Act with processes for the first biologic and for biosimilar approval. Prior to a dedicated approval pathway, biologics such as insulins, were approved through the existing pathway that is now only for small molecule drugs.[29]

There were 40 biosimilar products on the U.S. market as of December 2022.[30] The first U.S. biosimilar was approved in 2015. The first biosimilar in the EU was approved in 2006. There are 69 on the market in Europe.[31]



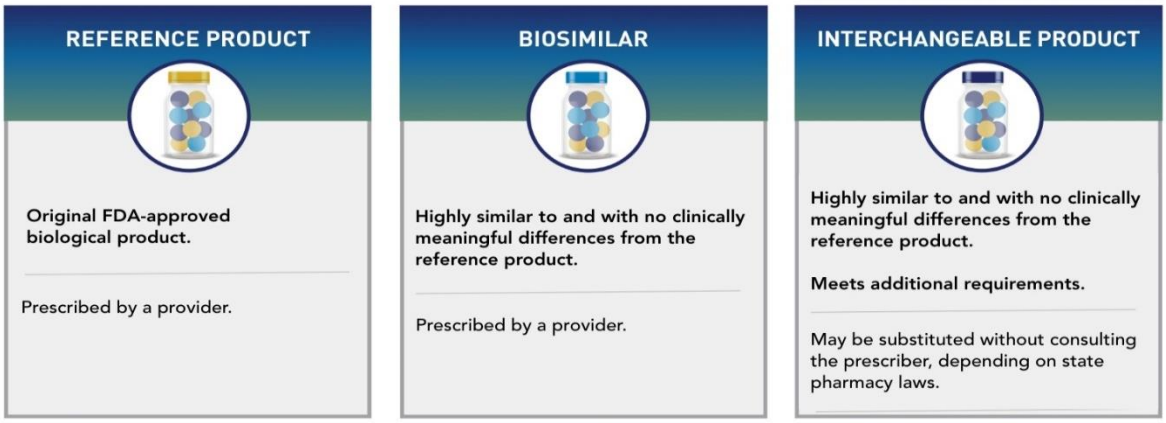
A molecule comparison of monoclonal antibody and aspirin shows the difference in large and small molecule drugs.[32]

Interchangeable biosimilars

FDA defines an interchangeable biosimilar product is a biosimilar which meets additional requirements outlined by the law that allows for the FDA to distinguish between biosimilar and interchangeable biosimilar medications.[33]

[29] "Review and Approval." U.S. Food & Drug Administration, Dec. 13, 2022. https://www.fda.gov/drugs/biosimilars/review-and-approval. Accessed April 11, 2023.
[30] "Biosimilar Product Information." U.S. Food & Drug Administration. Dec. 19, 2022. https://www.fda.gov/drugs/biosimilars/biosimilar-product-information. Accessed April 11, 2023.
[31] Figg, Anthony E., et al. "How the U.S. Compares to Europe on Biosimilar Approvals and Products In the Pipeline." Biosimilars Law Bulletin, March 14, 2022. https://www.biosimilarsip.com/2022/03/14/how-the-u-s-compares-to-europe-on-biosimilar-approvals-and-products-in-the-pipeline-updated-march-14-2022/. Accessed April 11, 2023.
[32] "Overview for Health Care Professionals." U.S. Food & Drug Administration, Dec. 13, 2022. https://www.fda.gov/drugs/biosimilars/overview-health-care-professionals. Accessed April 11, 2023.
[33] "Biosimilar and Interchangeable Biologics: More Treatment Choices." Consumer Updates, U.S. Food & Drug Administration, Oct. 12, 2021. https://www.fda.gov/consumers/consumer-updates/biosimilar-and-interchangeable-biologics-more-treatment-choices. Accessed April 12, 2023.

An interchangeable biosimilar product may be substituted without the intervention of the health care professional who prescribed the reference product, much like how generic drugs are routinely substituted for brand name drugs. This is commonly called pharmacy-level substitution and is subject to state pharmacy laws.



A comparison of reference products, biosimilars, and interchangeable products.[34]

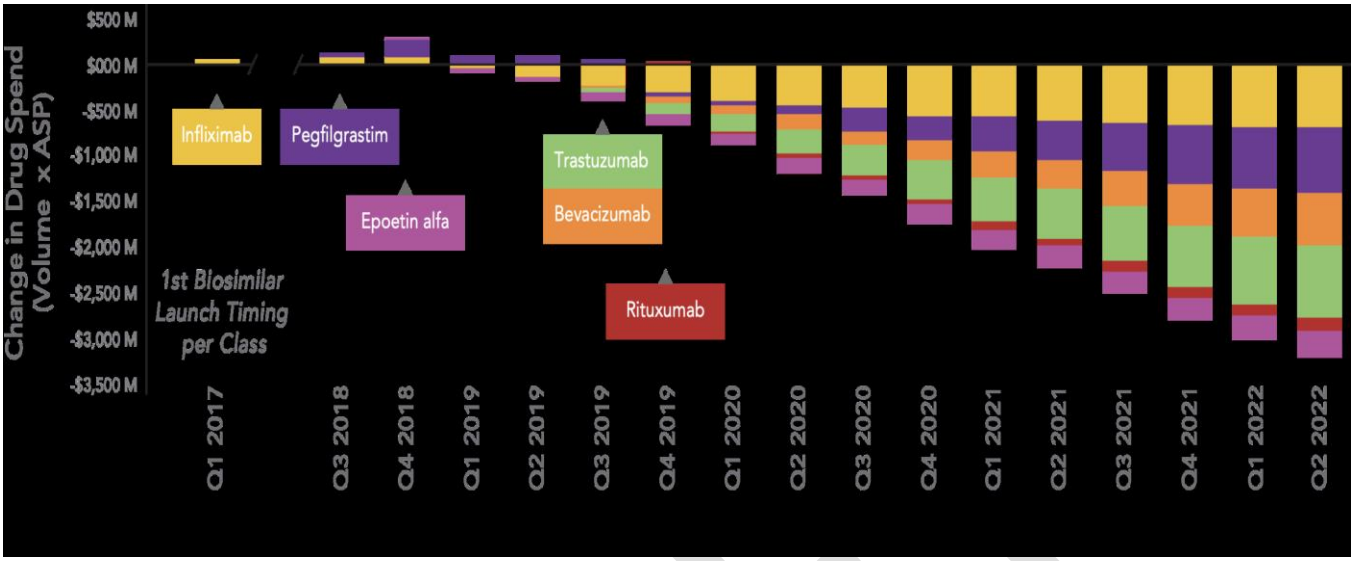
Cell and gene therapy biologics

FDA defines cell and gene therapies as therapy that modifies or manipulates the expression of a gene or to alter the biological properties of living cells for therapeutic use.[35] FDA has approved both cellular and gene therapy products which are regulated in the FDA Center for Biologics. Gene and cell therapies can use a patient's own cells that are modified and returned to the patient. Treatments can mitigate or cure a person's inherited disease. There are 27 approved cell and gene therapies. These one-time therapies can and do cost millions of dollars for a one-time treatment. [36]

Biosimilar costs and savings

Biologic products are much more costly to manufacture than small molecule chemical products. Biologics do not achieve the same manufacturing efficiencies as small molecules because the process is complex and remains complex for each batch of product. Biosimilars saved $7 billion nationally in 2021 and $13 billion since the first biosimilar was approved in 2015.[37] This graphic shows the impact of biosimilar competition on reference biologics using Amgen reference products.

[34] "Overview for Health Care Professionals." U.S. Food & Drug Administration, Dec. 13, 2022. https://www.fda.gov/drugs/biosimilars/overview-health-care-professionals. Accessed April 11, 2023.
[35] "Approved Cellular and Gene Therapy Products." U.S. Food & Drug Administration. Dec. 16, 2022. https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products. Accessed April 11, 2023.
[36] Ibid.
[37] "U.S. Generic and Biosimilar Medicines Savings Report: Generics and biosimilar medicines deliver more savings every year." Association for Accessible Medicines, September 2022. https://accessiblemeds.org/resources/blog/2022-savings-report. Accessed April 10, 2023.



Estimated Change in Total Drug Spend for Amgen Biologics After Biosimilar Competition [38]

Biosimilar market uptake

The actual use of biosimilar has been slower than hoped. There are several reasons for this. One reason is clinician reticence to use a biosimilar without full knowledge or trust that the treatment will have the same clinical outcome as the reference product. This is where the designation as interchangeable is important to improve uptake of biosimilars.

In addition to prescriber reticence, reference product makers encourage use of reference products over biosimilar competitors, similar to branded efforts to thwart generic uptake. Reference product sponsors provide tens of thousands of dollars to individual patients to buy down the patient's out of pocket costs for the reference product. Biosimilars often do not have the financial ability to compete on patient assistance without raising their market price. In the face of biosimilar competition, reference product sponsors will also offer very high rebates as incentive for the PBM to keep the biosimilar off the formulary in favor of the reference product. In this instance, the PBM and insurer reduce the net cost of the reference product below the cost of the biosimilar. Here again, the biosimilar company may not have the ability to compete on rebates without raising their list prices.

In addition to FDA efforts to designate interchangeable products, states have been creating laws for biosimilars substitution patterned after mandatory/voluntary generic substitution at the pharmacy. Oregon has had a biosimilar substitution law since 2016. It was updated in 2019. Most states have generic substitution laws and have for years. As of June 2019, the majority of

[38] "2022 Biosimilar Trends Report." Amgen Biosimilars, 2022. https://www.amgenbiosimilars.com/commitment/-/media/Themes/Amgen/amgenbiosimilars-com/Amgenbiosimilars-com/pdf/USA-CBU-81397-2022-Amgen-Biosimilars-Trend-Report-Oct-2022.pdf. Accessed April 11, 2023.

states have enacted laws concerning the substitution of a lower cost, interchangeable, biosimilar product for the reference biologic. About 35 states have enacted biosimilar substitution laws as of 2019.

Most of the state biosimilar substitution bills and laws are permissive. The pharmacist may offer to substitute a biosimilar if 'dispense as written' is not on the prescription. There may be other requirements that precede the substitution. There may be requirements that apply after the substitution has been made, such as notifying the prescriber within a set period of days about the substitution. A few states require the specific affirmation from a prescriber that substitution is permitted before substitution can occur. Some of the laws require prescription pads to have a checkbox for "dispense as written" and a check box for "substitution allowed." In some states that require a substitute biosimilar, pharmacists can only do so if the "substitution allowed" box is checked. In other words, lack of a "dispense as written" indication is not sufficient for biosimilar substitution in some states.[39]

Some states require the pharmacist proactively offer information about lower cost biosimilars without requiring a substitution. Mandatory substitution of a biosimilar for the reference product seems to be almost always subject to the permission of the patient in addition to any other requirements that limit dispensing.

Another approach to improving biosimilar uptake is reimbursement. Included in the federal Inflation Reduction Act of 2022 was a change in how Medicare Part B will reimburse for biosimilars.[40] Before the Inflation Reduction Act change, providers were reimbursed for the administered biosimilar at the average sales price (ASP) of the reference product plus 6 percent. Per the new law, providers will be reimbursed ASP plus 8 percent for the biosimilar if the biosimilar manufacturer average sales price is less than the ASP of the reference product. This incentivizes the provider to use the biosimilar and requires the manufacturer to keep the biosimilar price below the original reference product. This counters the possibility that biosimilars come to market priced close to the reference product in order to offer rebates for instance. The Medicare change to plus 8 percent means the Medicare patient will pay a bit more out of pocket for the biosimilar relative to ASP plus 6 percent.[41]

As more biosimilars come to market, the threats to reference products become more acute, which is why all these reference product market strategies have been developed. Biosimilar companies are responding by bringing their biosimilar to market at two different list prices, a

[39] Horvath, Jane. Horvath Health Policy, April 2023.
[40] Cohen, Joshua. "Inflation Reduction Act Provision Aims To Further Spur Biosimilar Uptake With Temporary Add-On Payment In Medicare Part B." Forbes, Oct. 5, 2023. https://www.forbes.com/sites/joshuacohen/2022/10/05/inflation-reduction-act-provision-aims-to-further-spur-biosimilar-uptake-with-temporary-add-on-payment-in-medicare-part-b/?sh=42c2a0c77bcd. Accessed April 12, 2023.
[41] Horvath, Jane. Horvath Health Policy, April 2023.

high price with rebates to PBMs and health plans, and a lower price for health plans and PBMs willing to pay less to reimburse providers and forego rebates.

This phenomenon affects drugs other than biosimilars. Amgen started this two-price market strategy when it launched its very expensive biologic treatment for familial hyperlipidemia, Repthatha. Amgen has reprised the strategy for its biosimilar Amjevita which will compete with Humira and other Humira biosimilars.

Impact of generics and biosimilars on healthcare spending and insurance premiums

The Association for Accessible Medicines found that Oregon, in total, saved $3.6 billion in drug costs due to generics and biosimilars in 2021.[42] Nationally, generics saved the US health system $366B and biosimilars saved $7 billion in 2021.[43]

Data is not currently available for determining the impact of generics and biosimilars on Oregon insurance premiums. There is little national data available about generic and biosimilar impact on insurance premiums specifically. The impact on premiums of small molecule generics in any one year would depend on the number of brands losing expiration, the amount that a plan spent on the brand(s) in the prior years before expiration and the percentage of plan spending dedicated to the patented products before expiration and the speed with which multiple generics enter the market.

Determining the impact of biosimilars on health insurance premiums will require information similar to the information required to understanding the impact of biosimilars on insurance premiums. Because biologics are so expensive, the impact of biosimilars may be more readily apparent than the impact of generics. The Maryland PDAB published a report of the small-molecule generic market in June 2020.[44] Their key findings were:

- Generic drug prices are generally stable year to year despite large increases for certain products.
- Generic drugs prices have minimal impact on insurance premiums.
- Cost sharing for generic drugs is stable. Drug shortages adversely affect patients.
- The available data did not allow a determination of the impact of generics on Medicaid.

[42] "Generic and Biosimilar Medicines Save Oregon Patients Billions." Biosimilars Council, a division of Association for Accessible Medicines. https://accessiblemeds.org/sites/default/files/2023-01/AAM-2022-generic-biosimilar-savings-Oregon.pdf. Accessed April 11, 2023.
[43] Ibid.
[44] "Study of the Operation of the Generics Drug Market." Maryland Prescription Drug Affordability Board, June 1, 2022. https://pdab.maryland.gov/documents/pdab_study_of_Operation_of_the_Generic_Drug_Market.pdf. Accessed April 11, 2023.

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