Oregon Prescription Drug Affordability Board

Oregon Prescription Drug Affordability Board Meeting
Wednesday, April 19, 2023 Minutes
Approved on May 17, 2023

Chair Akil Patterson called the meeting to order at 9:35 am and asked for the roll call.

Board members present: Chair Akil Patterson, Vice Chair Shelley Bailey, Dr. Richard Bruno, Dr. Daniel Hartung, Robert Judge (alternate).
Board members absent: Dr. Amy Burns, John Murray (alternate), Dr. Rebecca Spain (alternate).

Chair Akil Patterson asked if board members had any changes to the March 15, 2023, minutes on Pages 3-6 in the agenda packet: https://dfr.oregon.gov/pdab/Documents/20230419-PDAB-document-package.pdf and there were none. **Dr. Richard Bruno** moved to approve the minutes and **Robert Judge** provided a second.

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

Program update: Executive Director Ralph Magrish welcomed Amanda Claycomb, research analyst, to the PDAB team. Staff held interviews for the data analyst position and anticipate introducing a new person next month. Staff has executed a contract with Jane Horvath of Horvath Health Care to provide policy and technical assistance. In May, the board will hear a presentation from AHIP, the trade association for insurance carriers. Ralph introduced Sarah Emond, executive vice president and chief operating officer of Institute for Clinical and Economic Review (ICER).

Sarah Emond, EVP and COO, Institute for Clinical and Economic Review (ICER), gave a presentation from Pages 7-19 in the agenda document about the nonprofit organization, independent of industry, doing health technology assessments. ICER does analyses of new drugs, looking at comparative clinical effectiveness, and whether price increases are supported by new evidence. She provided a list of ICER funding sources. She provided a link to a recent paper about using health technology assessments to advance health equity. ICER will evaluate clinical trial diversity and provide a rating for how well the clinical trial did in recruiting and studying the drug in a population that matches the prevalence for the disease. ICER will use a Health Improvement Distribution Index to estimate the impact a new treatment could have in addressing overall health disparities. In conjunction with the disability community, ICER has developed an alternative metric to quality-adjusted life years (QALY) to ensure ICER is valuing life extension the same for every patient, regardless of disability or status. The equal value of life years gained (evLYG) metric is available in every ICER report and can be used to help know what a fair price is for a new medicine. All of ICER reports are publicly available.
Shelley Bailey asked if the estimated discount on Slide 9 takes into consideration the 340B pricing, whether it was part of the net pricing, and whether more discounts were needed beyond 340B to achieve those goals?
Sarah Emond said it is difficult to know net prices of medicines because they are held as proprietary trade secrets between the plans and manufacturers. ICER uses a source called SSR Health, an independent consultant that estimates net based on volume and net revenue information reported by companies. It is all one big bucket and impossible to know whether it is 340B, rebates to PBMs, or patient assistance programs, she said. **Ralph Magrish** said in addition to having a license with ICER, staff has executed one with SSR Health.

Daniel Hartung asked how responsive manufacturers and industry are to some of the value metrics that ICER produces with different payers? From the payer perspective, how common is it for ICER reports to be used by payers to leverage discount price negotiation with manufacturers? **Sarah Emond** said industry is at the table, engaging, advocating for the value of their medicines. With only a few exceptions, manufacturers participate in the ICER review, providing data and comments on the economic model. Manufacturers do the same analyses that ICER does, including cost-effectiveness models and comparative clinical effectiveness. Manufacturers have cited ICER research in justification for their own price and private payers cite ICER work for coverage policy, price negotiations, or deliberations. About three-quarters of Medicaid departments rely on ICER's work. New York has leveraged ICER work to get about $500 million in supplemental rebates for their Medicaid program.

Richard Bruno asked for more detail on equal value of life years gained (evLYG) and how it compares to QALYs or other similar metrics and how that works with certain populations. **Sarah Emond** said the metric known as quality adjusted life year (QALY) was developed decades ago by American physicians and health economists to measure how much a drug improves quality of life and longevity. It has a limitation, which is, if there is a condition that extends life for a population with an underlying illness, comorbidity, or disability, an analysis could undervalue time and life extension. ICER uses the equal value of life years gain (evLYG) metric measures the time and life extension the same, no matter who a person is. ICER picks a point, a value, and everyone gets assigned that value. Decision makers can still highly value drugs that are delivering great improvements in quality of life and length of life and then protect against undervaluing drugs that extend the life of people with underlying disabilities.

Shelley Bailey asked if ICER gets the total cost of the disease data from payers or if there is another data source for total cost of the disease versus offset of the cost of the drug? **Sarah Emond** said ICER uses national averages for costs, including Medicare data, claims databases, and other sources. Patient advocacy organizations are excellent sources because they have done their own research on natural history and cost of care.

Daniel Hartung: What about weighing value metrics with budget impact of drugs that are a really good value but still budget busters? A lot of people need care – how does ICER grapple with those competing resource issues? **Sarah Emond**: In every analysis, ICER emphasizes the long-term value for money and benefit for patients over a lifetime. But for decision makers, affordability is an important component. ICER reports include a budget impact analysis, which sets the threshold for an increase in spending on a per-member-per-month basis, which is about twice the rate of medical inflation. If ICER predicts a potentially high-value, high-cost intervention would impact the ability of insurers and employers to offer affordable health insurance, ICER signals that alert so policymakers can talk about ways to manage that budget impact. Follow up options could include targeting the sickest patients, trying to get additional discounts for a particular drug, or using the ICER budget impact model tool to determine if the introduction of a particular drug would mean a budget impact for a state, she said.

Legislative Update: Jessie O'Brien, policy manager for the Division of Financial Regulation, gave a status of proposed bills being considering by the Oregon Legislature in the 2023 Session. See the summary on Pages 20-21 of the agenda packet, with links to the bills.

Rulemaking Advisory Committee: **Cortnee Whitlock** reviewed the notes and summary from the rulemaking advisory committee meeting held April 5. See the notes and summary on Pages 22-26 of the agenda packet. She said the public hearing will be held June 22 and public comment will be accepted through June 29.

Draft Affordability Review Rule: Cortnee Whitlock reviewed the draft affordability review on Pages 29-51 of the agenda packet, beginning with Section 3(a). The process begins by looking at the data provided by the Drug

Price Transparency (DPT) Program. Staff will take the top 25 drug lists from DPT and categorize them into high-level medications consistent on all reports. From there, the board will use the criteria in the rule to funnel down the data. She asked if board members had feedback. This table summarizes board member feedback:

Feedback	Rule Section	Board Member
* Expand insulin data to include current price increases since data is two years old.	(3)(a) C	Robert Judge
* Option 2 in F, CMS Medicare negotiation list. * Remove F or soften language (instead of "eliminate," use "not including"). * Hold off F until CMS negotiations go live.	(3)(a) F	Robert Judge, Daniel Hartung, Shelley Bailey
* Remove G, FDA shortage list. *Notes*: No need for drug shortage list criteria considering this board will not yet have upper payment limit authority. Often, when drugs come off the FDA approved shortage list, they have a considerable price increase.	(3)(a) G	Akil Patterson, Shelley Bailey, Robert Judge
*Option 2 in H, patent expiration dates, within 18 months instead of 3 years. *Notes*: Three years is a lifetime. Needs a narrower window. Board would miss potential opportunities for cost savings.	(3)(a) H	Akil Patterson, Shelley Bailey, Daniel Hartung, Robert Judge
*Add the word *net*: Changes in the prescription drug *net* wholesale acquisition cost over time."	(4)(b) C	Shelley Bailey
* Add information about the total cost of the disease and the drug price offset	(4)(b) G	Shelley Bailey
* Add language about rebates, discounts, and price concessions that 340B price concessions are part of. *Notes*: Patient assistance and coupon rebate paperwork is a very onerous process for patients.	(4)(b) K	Shelley Bailey, Richard Bruno
* Add definition of price to clarify the meaning.	(4)(b)	Robert Judge

Generic Drug Report: Cortnee Whitlock reviewed the draft report located on Pages 52-66 of the agenda packet. She asked if board members had any changes, and there were none. She asked Robert Judge if his earlier request to include a section on biologic and biosimilars was addressed in the draft report, and he said yes. The report will be in the May meeting packet for final approval by the board.

Public comment: The chair allocated three minutes for public comment. Dharia McGrew, regional vice president PhRMA, provided testimony to the board. PhRMA's written comments are posted online: https://dfr.oregon.gov/pdab/Documents/20230419-PDAB-public-comment.pdf.

Adjournment: The meeting was adjourned at 11:23 a.m. by Chair Akil Patterson, with a motion by **Richard Bruno** and a second by **Shelley Bailey**.