Senate Committee on Health Care

Re: SB 457 – Oregon HERC and P&T Process and Transparency

Chair Patterson, Members of the Committee;

We thank you for considering SB 457. Oregon is a leader in providing affordable health care for the most vulnerable Oregonians. The Oregon Health Plan, and our state implementation of Medicaid are designed to ensure equal access to the best treatment, including new, approved innovations. However, our evidence-based approach to medical assistance needs updates to ensure transparency, good governance and reflect modern medicine and technology.

Our organizations represent thousands of large and small biotech companies throughout the country - including in Oregon. Our members span from those engaging in foundational research, to entrepreneur, to major manufacturers and developers of therapies, cures and devices. The pillars of our organizations are to be a voice of science and for science, unite and empower biotech innovators and their ecosystem, improve lives, remove barriers to innovation, champion broad access to biotech breakthroughs and scientific equality, and catalyze resilient and sustainable bio-based economies.

Over the past several years, our members, and the patients and providers they work with are experiencing more difficulty in interfacing with Medicaid coverage decisions. The Health Evidence Review Commission (HERC) and Pharmacy & Therapeutics Committee (P&T) make critical decisions that allow access to new treatments and determine the pathway to coverage for our most vulnerable Oregonians. Flaws in the process and limitations of the evidence used to support coverage decisions can have troubling results: coverage for those with private insurance but gaps for those on state medical assistance. SB 457 and our proposed amendments address several of these concerns.

Process and Transparency

Improving the HERC and P&T notification process, restricting limitations on submissions and addressing committee make-up are simple steps that would enhance the public's trust in Medicaid coverage decisions. SB 457 explicitly requires that each body includes an expert in the specific condition under review as a voting member. Practicing physicians or researchers in a field are a critical component to ensuring the coverage criteria for a particular procedure, device or therapy is considered appropriately. Further, SB 457 prohibits word limits or restrictions on testimony, simple good governance to ensure that all evidence and input is provided to the HERC and P&T. In the past, nationally renowned experts have flown across the

country, then restricted to three-minute testimony without Commissioners' ability to engage in a question and answer with the expert. SB 457 provides a longer notification period for proposed changes, giving stakeholders adequate time to analyze and respond to changes that can have significant impacts on the services available to Oregon's Medicaid population.

SB 457 also addresses several issues related to serving members on the HERC and P&T. As with any governmental oversight board, SB 457 implements term-limits for each body. Several members have served for many years, at times creating an environment where members defer to senior serving Commissioners on technical issues and how the agenda is set and managed. Term limits would require fresh thought and direction for each board. Further, SB 457 would address conflicts where the Commissioners have either a professional stake in the outcome, based on published works or compensation from their employer, ensuring that decision are unbiased and strictly evidence-based.

Evidentiary Considerations

Access to innovation is core value or our organizations. As gene therapies, personalized medicine and new diagnostic tools grow and emerge, it is important that the HERC and P&T staff recommendations reflect the entire body of evidence for particular conditions and treatments. In recent years, staff has relied heavily on published studies, thereby conflating "publications" and "evidence." While published studies based on randomized controlled testing are the gold standard for evidence-based medicine, there are times when significant observational data, clinical trial results and even provider expertise can differ for a variety of reasons. The HERC and P&T should see the full realm of evidence considered in approving, declining or authorizing a particular treatment.

Limiting the realm of reliable evidence creates a magnified disparity in coverage for those with rare conditions or needing new therapies. New treatments naturally have less published academic reviews, but the results of clinical trials and experience of providers can establish the value and effectiveness of a new treatment. In addition, with many conditions, particularly degenerative diseases or those impacting children, randomized controlled testing is often unavailable or unethical (and the FDA has allowed for new evidentiary pathways for approval). Our proposed amendments address this problem as well.

Amendments

As noted, BIO and Oregon Bio are supporting amendments to SB 457. Our amendments remove several sections related to prior authorization for prescription drugs under the state's Medicaid program (Sections 1-3). They also address the term limits described above and bolstered evidentiary standards for the HERC and P&T. Finally, our proposed amendments would ensure that CCO's would comply with similar transparency, process and evidentiary requirements so that all Oregonians have the same access to the best evidentiary process for coverage determinations.

We thank the Committee for its consideration of these much-needed improvements to Oregonians medical assistance programs. We look forward to continued discussions with the committee, the Oregon Health Authority and other stakeholders.

Sincerely,

Liisa Bozinovic
Chief Executive Officer
Oregon Bioscience Association

Brian Warren
Director, State Government Affairs
Biotechnology Innovation Organization