March 17, 2025

The Honorable Rob Nosse, Chair
House Behavioral Health and Health Care Committee
State Capitol, 900 Court St NE
Salem, OR 97301

Dear Representative Nosse and Members of the Committee:

The Biotechnology Innovation Organization (BIO) and the Oregon Bioscience Association are pleased to support HB 3241, which would require health plans to include coverage for biomarker testing, as specified. Our organization's support timely, appropriate, and equitable access to biomarker testing as well as adequate coverage and reimbursement by public and private payers when backed by clinical guidelines or peer-reviewed scientific evidence. Delays in biomarker testing and coverage may lead to worse outcomes for patients.

Continuing advances in science and genomics are driving an increased understanding of human physiology and how diseases affect the body; these advances are helping researchers identify new biomarkers. As more biomarkers are identified, they have the potential to greatly enhance the drug development process by providing researchers with new ways to measure disease activity, reduce the amount of time required to show a medicine is safe or effective, and enable the development of more personalized, precision medicine—particularly where multiple biomarkers can inform the use of targeted drug combinations. Biomarkers can also allow researchers to better understand how effective a treatment is against a disease with endpoints that are difficult to define, providing clinicians with additional informative measurements in the early diagnosis of a disease and identifying differences in responses between individuals or subpopulations.

The development of personalized medicines that are more tailored to the individual patient using biomarkers helps drive efficiencies and improvements in patient care. Biomarkers can help identify patients most likely to benefit from a specific treatment. For example, biomarkers are often used in cancer treatments to identify patients with tumors expressing certain genetic characteristics that indicate those patients are likely to respond to a targeted cancer therapy. In another example, they can be used to ensure that a certain patient with a rare disease will most likely benefit from a specific therapy, particularly gene therapy.

Access to biomarker testing should not be delayed, as this may have detrimental effects on patient outcomes. If patients do not have access to biomarker testing, they will not know about life-saving targeted therapies that can improve their overall health outcome. Additionally, it is important that if access to a particular therapy is dependent upon specific biomarker, coverage and testing policies must immediately reflect the new advances in treatment. Coverage policies should never stand in the way of access to treatment.

The identification of biomarkers is not done through at home genetic DNA testing. It is done in a medical setting by healthcare professionals and clinicians within the scope of their license and experience to identify appropriate biomarkers for clinical trials. In addition, genetic counselors guide patients through proper clinical treatment guidelines and options. These health professionals must always have the ability to order all comprehensive biomarker testing panels necessary to ensure appropriate treatment and continuing care. Sadly, a February 2022

report by Milliman found that 48 states have no minimum coverage requirements for biomarker testing.[1]

BIO and Oregon Bioscience Association support the continual assessment of coverage requirements by public and private payers for novel biomarker testing that come to market. Additionally, public, and private payers should regularly review clinical guidelines, existing medical compendia, CMS coverage guidelines, recommendations of health professional organizations, and consensus statements to update their testing policies.

Biomarker testing should not be subject to lifetime limits. As disease stages progress over time and can vary from patient to patient, biomarker testing should be covered for all relevant panels of tests at any time in the continuum of care, if determined necessary by a health care professional.

For these reasons outlined above, we respectfully urge your YES vote on HB 3241.

Sincerely,

Liisa Bozinovic
Executive Director
Oregon Bioscience Association

Brian Warren
Vice President, State Government Affairs
Biotechnology Innovation Organization

[1] Dieguez, G., Carioto, J., *The landscape of biomarker testing coverage in the United States*. (2022).