HB 3421 STAFF MEASURE SUMMARY

House Committee On Behavioral Health and Health Care

Prepared By: Brian Nieubuurt, LPRO Analyst **Meeting Dates:** 3/20, 4/3

WHAT THE MEASURE DOES:

The measure requires health insurance policies, health care services contracts, the Oregon Health Authority (OHA), and coordinated care organizations (CCOs) to cover biomarker testing in specified circumstances.

Detailed Summary:

- Defines "biomarker," "biomarker testing," "clinical practice guidelines," "consensus statement," and "national recognized clinical practice guidelines."
- Requires health insurance policies and health care services contracts that reimburse the cost of laboratory services, as well as OHA and CCOs, to cover biomarker testing when testing is supported by United States Food and Drug Administration (FDA) approved tests, drugs, or drug labels; Coverage Determinations made by the Centers for Medicare and Medicaid Services; or national recognized clinical practice guidelines.
- Exempts insurance coverage requirement from automatic repeal.

FISCAL: May have fiscal impact, but no statement yet issued.

REVENUE: May have revenue impact, but no statement yet issued.

ISSUES DISCUSSED:

EFFECT OF AMENDMENT:

No amendment.

BACKGROUND:

Biological markers, or biomarkers, are objective measures of what is happening in a cell or organism at a given moment. Some biomarkers can be easy to measure (e.g. blood pressure), while others can require more complex testing of blood, urine, or tissues. Biomarkers can help gain a better understanding of what may be causing a disease (e.g. cancer), as well as what specific therapies may be most effective in combating that disease. The United States Food and Drug Administration has defined seven categories of biomarkers:

- Susceptibility/risk
- Diagnostic
- Monitoring
- Prognostic
- Predictive
- Pharmacodynamic/response
- Safety

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