

REVENUE: No revenue impact

FISCAL: Minimal fiscal impact, no statement issued

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Action: Do Pass  
Vote: 3 - 0 - 2  
Yeas: Knopp, Kruse, Monnes Anderson  
Nays: 0  
Exc.: Shields, Steiner Hayward  
Prepared By: Sandy Thiele-Cirka, Administrator  
Meeting Dates: 4/25

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**WHAT THE MEASURE DOES:** Authorizes pharmacy to perform certain tests and examinations if pharmacy obtains waiver from United States Department of Health and Human Services and complies with applicable federal regulations.

**ISSUES DISCUSSED:**

- Access and affordability
- Clinical Laboratory Improvement Amendments (CLIA) requirements
- Community pharmacists offering specific tests are CLIA waived
- Chronic disease monitoring
- Importance of regular testing

**EFFECT OF COMMITTEE AMENDMENT:** No amendment.

**BACKGROUND:** The Centers for Medicare and Medicaid Services (CMS) regulates laboratories under the Clinical Laboratory Improvement Amendments (CLIA). Some health tests are very simple, accurate and safe, that they are “waived” from CLIA requirements. To qualify as a “waived” test, it must: (a) be cleared by FDA for home use, (b) be so simple and accurate as to render the likelihood of erroneous results negligible, or (c) pose no reasonable risk of harm to the patient if the test is performed incorrectly. Facilities that perform only CLIA-waived tests must obtain a Certificate of Waiver from CMS and follow manufacturers’ instructions when performing the tests.

House Bill 2714 allows pharmacies in Oregon to apply for this waiver to perform approved tests.