

Oregon Community Pharmacy Council
Oregon State Pharmacy Association
Oregon Society of Health-System Pharmacists
Walgreens

National Association Chain Drug Stores
Northwest Grocery Association
Safeway
Rite-Aid

Please Vote YES on HB 2714

Chronic diseases – such as heart disease, diabetes and hypertension – are among the most common, costly, and preventable of all health problems in the U.S. Certain chronic diseases may not exhibit symptoms and, when left untreated, can lead to significant increases in preventable death, disability, and healthcare costs.

Purpose

The legislation is intended to remove unnecessary regulations in order to improve efficiency in the healthcare delivery system. Specifically, this bill would allow pharmacists to perform over-the-counter laboratory tests, such as glucose level or cholesterol tests, without the need to hire a laboratory director. Pharmacies are not looking to become laboratories, so this bill would allow pharmacists to perform only specific tests that are already recognized by the FDA as safe to be performed with little or no oversight. This legislation will result in easier access to safe, simple, and economical tests—especially for low income individuals, less crowding in physicians' offices, and an improved ability of pharmacists to provide meaningful feedback to their patients when providing drug consultations.

Background

Both state and federal laws regulate clinical laboratory tests. The Centers for Medicare and Medicaid Services (CMS) regulates laboratories under the Clinical Laboratory Improvement Amendments (CLIA). Some health tests are so simple, accurate and safe that they are “waived” from CLIA requirements. To qualify as “waived” a test must (a) be cleared by FDA for home use, (b) employ methodologies that are 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 (42 CFR 493.15). Facilities that perform only CLIA-waived tests must obtain a Certificate of Waiver from CMS and follow manufacturers' instructions when performing tests.

All tests provided by community pharmacists are CLIA-waived, including the common tests such as blood glucose, A1C (diabetes), cholesterol and lipid panels, and body composition. In addition, community pharmacists may also provide consultation as to the results and follow-up with a primary care provider.

Need for This Bill

With the rise of chronic disease, many providers and national organizations recommend regular health testing, and the convenience of community pharmacists increases the public's access to this vital service. Health tests can identify problems before they start and monitor and maintain a person's health status. They can also interrupt the disease process at a point when health and daily living can be preserved or more fully restored and medical and other related costs are less. In addition, the New England Healthcare Institute states that “poor medication adherence is exacting a heavy toll in the form of unnecessary illness, disability and premature mortality, particularly among the burgeoning number of chronically ill patients in the U.S. Poor medication adherence in all its manifestations costs the U.S. upwards of \$290 billion per year in unnecessary health care spending.” Medication non-adherence occurs among patients for a number of reasons, many of which involve substandard therapy.

These tests that can help patients and their pharmacists monitor therapy and disease. With the results of these tests, appropriate adjustments to treatment can be made in a timely manner, helping to improve medication adherence and overall treatment. With 90% of chronic conditions requiring medication as a first-line treatment, improving medication therapy is essential. The Oregon Community Pharmacy Council recommends aligning state laws and regulations with federal CLIA waiver requirements, expanding patient access to pharmacist-provided health tests.

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