

### PHARMACISTS' SCOPE OF PRACTICE

Expansion of diagnosing and prescribing authority does not increase access to care.

Virginia law currently allows a pharmacist to collaborate with a physician, physician assistant, or nurse practitioner to be able to provide drug therapy treatment or lab tests and exams.

HB 1506/SB 1026 would end team-based care.

# The Problem: Testing is Not Diagnosis

Pharmacists are seeking to expand their scope of practice to diagnose and prescribe epinephrine; prescription tobacco cessation products; TB tests;

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tests and medications for flu, strep, urinary tract infections, and H. Pylori; contraceptives; PrEP for HIV, and more.

Diagnosing and treating even seemingly simple diseases can be complicated.

## The Solution: Physicians remain the best health care provider to diagnose and treat illness.

Patients receive the best care when care delivery aligns with a provider's education and training. Pharmacists are trained to be experts in medications; physicians are trained to be experts in diagnosis and treatment of health conditions.

- CLIA-Waived tests do not guarantee an accurate and complete diagnosis.
- Diagnoses made without a physical exam or medical history can be potentially harmful to a patient.

### **CLIA-waived tests are not error-proof.**

- Diagnoses made without a physical exam or knowledge of patient history can be potentially harmful to a patient.
- CLIA waived tests cover a wide spectrum of tests that screen for a 'marker' which may cause several different illnesses or diseases.
- Testing should not occur without a full patient assessment by a qualified health care provider or patients may be misdiagnosed.

### Q: What are CLIA-Waived Tests?

Lab testing that employs specific test methods designated under the Clinical Laboratory Improvement Amendments (CLIA) of the Food and Drug Administration (FDA) as "waived." These tests screen for a 'marker' which may indicate several different illnesses or diseases and require further patient assessment.

### Q: How would pharmacists diagnosing the following illnesses negatively impact care?

#### FLU

Flu is the 8<sup>th</sup> leading cause of death in the US and is a common cause of pneumonia, especially among younger children, the elderly, pregnant women, or those with chronic health conditions. Cases of flu which lead to pneumonia tend to be most severe and deadly. Often, flu and pneumonia can present the same; specific medical tests need to be conducted to determine if a patient has pneumonia. Tamiflu is not always appropriate for patients with the flu and in some cases additional medical care may be needed.

### **STREP**

Strep diagnosis is more complicated than just doing a swab. There are patients who are "Strep carriers" who may test positive but Strep is not the cause of their symptoms. The 'Strep test' actually tests for a bacteria which can cause strep throat, but could also cause tonsillitis, scarlet fever, acute rheumatic fever, streptococcal toxic shock syndrome (STSS) and necrotizing fasciitis (Flesh Eating Bacteria).

Misdiagnosing a patient can lead to unintended consequence and potentially harmful outcomes.

### **TOBACCO CESSATION**

Treatment for tobacco product use can range from therapy programs to medication. Chantix is a popular prescription for treating addiction to the use of tobacco products and requires a medical assessment for safe use. Chantix may worsen existing kidney issues and in severe cases, cause renal failure if testing is not conducted to assess proper kidney function and related diseases are not ruled out. Chantix can also cause new or worsen existing heart conditions. Labs and testing can prevent cardiovascular complications when done by a physician.

When addressing an issue such as addiction, mental health should play a vital role in treatment. Chantix can cause aggression, depression, or suicidal thoughts and actions. Every patient subject to side effects such as these should have access to a medical professional for counseling and follow up care.

### HIV

The CLIA-Waived HIV test has several limitations that can lead to a false negative or a false positive. The FDA warns that "a nonreactive test result does not preclude the possibility of exposure to HIV or infection with HIV. An antibody response to recent exposure may take several months to reach detectable levels." Additional labs, beyond CLIA-Waived, are necessary to determine the stage of the disease and proper treatment. Physicians have the necessary training to perform these tests, such as CD4 T cell count, viral load, and drug resistance, and to determine the best course of treatment. Receiving a positive HIV diagnosis can also be extremely emotionally difficult; patients need to be connected with care that supports their physical and mental health.

For more information, please contact Clark Barrineau at cbarrineau@msv.org