

Maryland General Assembly
Bill Nos. [SB 0706](#) & [HB 0810](#)

*Ordering & Administering
Certain Laboratory Tests
by Pharmacists*

February 2021



Outline



- **What are clinical lab tests and why expand their access? Why now?**
- **Who can order clinical lab tests today? What types of tests can Md. pharmacists currently order?**
- **What role are pharmacies playing in the pandemic response?**
- **Key provisions of SB 0706 & HB 0810**
- **Safeguards and Patient Protections**
- **Who is supporting this legislation?**



Comparing Lab Tests to Rapid Tests

	Laboratory Tests	Rapid Tests
<i>Specimen Collection Location</i>	Clinic or Pharmacy	Clinic or Pharmacy
<i>Analysis Location</i>	Clinical Laboratory	Clinic or Pharmacy
<i>Accuracy / Sophistication</i>	High / High	Moderate / Low
<i>Time for Results</i>	~1 to 2 days	~10 minutes
<i>Regulation</i>	CLIA (CMS & States)	FDA
<i>No. of Marketed Test</i>	~100,000	~1,000
<i>Examples (Pandemic Related)</i>	Covid-19 Virus (PCR) Testing	Covid-19 Antibody & Antigen Testing



Who Can Order Lab Tests in Maryland Today?

[Code of Maryland Regulations 10.10.06](#)

- Doctor of medicine, osteopathy, podiatric medicine, or dentistry (tests not limited to medical specialty)
- Nurse midwife
- Nurse practitioner or physician's assistant
- Chiropractor (blood or urine)
- Employer (job-related test for alcohol or controlled substances)
- **Pharmacist, but only for tests that qualify for a letter of exception under [COMAR 10.10.03.02B](#) and for glucose, A1c, lipids (including total cholesterol, HDL, LDL, and triglycerides), AST, and ALT (expanded in Spring 2020 to include Covid-19 tests)**



Pharmacies Help Meet the Urgent Demand for Covid-19 Testing

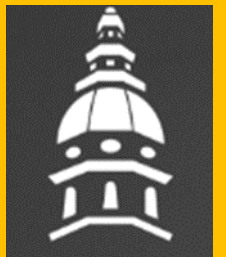
GOVERNOR HOGAN ANNOUNCES
**BROADENED CRITERIA
FOR TESTING, DRAMATIC
EXPANSION OF TESTING
AVAILABILITY STATEWIDE**

- » Authorizes and encourages licensed pharmacists to order and administer COVID-19 tests
- » Appointment-free testing in Maryland begins Thursday and Friday at select sites; two new VEIP sites opening in Prince George's County
- » Marylanders can now get tested even if asymptomatic
- » Maryland has now tested 3.5% of state's population, far exceeding goals established by federal health officials



HHS Assistant Secretary for Health Brett P. Giroir, M.D. ("Coronavirus Testing Czar") issued the following statement on 4/8/20:

"In an effort to expand testing capabilities, we are authorizing licensed pharmacists to order and administer COVID-19 tests to their patients. The accessibility and distribution of retail and independent community-based pharmacies make pharmacists the first point of contact with a healthcare professional for many Americans."



Why Expand Lab Testing at Pharmacies? Why now?



- Consumer demand for testing at pharmacies made clear throughout the pandemic
- Pharmacist deemed a trusted and know source for healthcare information by Marylanders
- Substantial innovation in laboratory developed tests occurred as a result of Covid-19
- An array of “long-haul” ailments predicted after coronavirus infections likely requiring novel tests and testing approaches
- Many routine screenings were missed during the pandemic creating need to catch-up to avoid late-stage diagnoses



Key Provisions of SB 0706 & HB 0810

[Click Link to Read Bill](#)

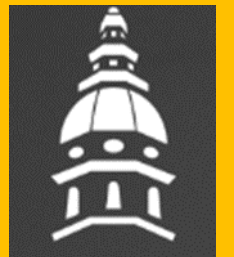
- Pharmacists, at their option, can order and administer certain health screening tests
- Pharmacy technicians help patient collect specimens such as capillary blood, saliva, etc.
- Specimens sent to CLIA laboratory for analysis
- Results reported to pharmacy and patient
- Abnormal results forwarded to patient's primary care provider
- Geared mainly to self-pay tests (unless 3rd party payer expressly authorizes pharmacy orders)



Safeguards & Patient Protections



- Limited to health screening tests (not definitive diagnostics)
- Out of range test results to be reported to patient's PCP or medical specialist
- Limited to bodily specimens that can be safely collected at a pharmacy
- Three-year pilot with sunset provision pending Board of Pharmacy review and report

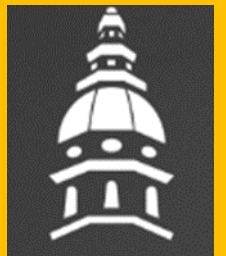
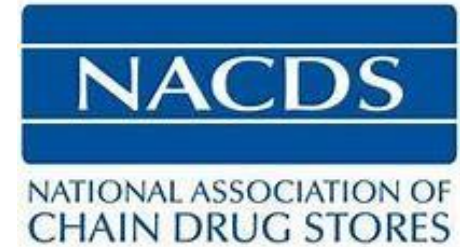


Organizations Supporting this Legislation

As of 2/9/21



MARYLAND ASSOCIATION
OF CHAIN DRUG STORES



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