



Pennsylvania Association of Chain Drug Stores



Empowering Pharmacists.
Transforming Aging.



May 27, 2020

Governor Tom Wolf
Office of the Governor
508 Main Capitol Building
Harrisburg, PA 17120

The Honorable Rachel Levine
Pennsylvania Secretary of Health
Health and Welfare Building, 8th Floor West
625 Forster Street
Harrisburg, PA 17120

RE: Request Laboratory Requirement Waiver: COVID-19 Testing by Pharmacists

Dear Governor Wolf and Dr. Levine:

On behalf of the undersigned state and national organizations representing pharmacy, we appreciate your leadership during the COVID-19 pandemic response and commend your focus on ramping up testing capabilities as the Commonwealth works to reopen its economy. We take this opportunity to explain the ways that community pharmacies could strongly support those efforts and the state-specific barrier preventing them from doing so. We request your immediate action to verify removal of a unique barrier in state law that prevents the 2,646 pharmacies in the Commonwealth from offering widespread community-based testing.

In support of this request, the U.S. Department of Health and Human Services (HHS) issued an advisory opinion on Tuesday, May 19th.¹ This new advisory opinion states that federal law, along with Executive Branch actions, preempts any state or local requirement that prohibits or effectively prohibits a pharmacist from ordering and administering end-to-end COVID-19 diagnostic test that the Food and Drug Administration (FDA) has authorized. You will recall that on April 8, 2020, the Office of the Assistant Secretary of Health within HHS issued guidance “authorizing licensed pharmacists to order and administer COVID-19 tests, including serology tests, that the [FDA] has authorized.” While this was a strong and clear statement in its own right, some questions appeared to remain regarding existing barriers at the state level, including state laboratory and biomedical requirements, but the new HHS advisory opinion appears to resolve those questions. Even so, we invite you to verify that by way of an executive order.

We applaud your earlier effort, on April 13th, publishing guidance granting pharmacists authority to conduct COVID-19 test with a Clinical Laboratory Improvement Amendments of 1988 (CLIA)-waiver. CLIA-waivers are regulated by the Centers for Medicare and Medicaid Services (CMS), and some states,

¹ Department of Health and Human Services (HHS). Advisory opinion 20-02 on the Public Readiness and Emergency Preparedness Act and the Secretary’s Declaration under the Act. May 19, 2020. <https://www.hhs.gov/sites/default/files/advisory-opinion-20-02-hhs-ogc-prep-act.pdf>

including Pennsylvania, have additional requirements. Unfortunately, your guidance did not remove all questions as to potential state-level barriers that would allow pharmacists to do such testing, leaving pharmacies in Pennsylvania in some doubt as to whether they can proceed to offer pharmacist-provided COVID-19 testing.

The major barrier that Pennsylvania pharmacists see as a concern to performing COVID-19 tests, and in conflict with your testing priorities, lies in the Pennsylvania Clinical Laboratory Act. This Act dating to 1951 (Sept 26, 1951, PL 1539, No. 389), requires even doctorate-level pharmacists to have two years of laboratory work experience. Not only does this go beyond federal requirements, based on our research, no other state requires such experience, including the neighboring states of Ohio, West Virginia, Virginia, Maryland, and Delaware.

Pharmacists in community pharmacies are prepared, trained, and accessible. Community pharmacy-based, CLIA-waived testing for infectious diseases, including influenza, group A streptococcus, HIV, and hepatitis C has been a well-established practice for many years and is already occurring throughout the country in more than 40 states. In at least 17 of the 40 states, pharmacists can initiate treatment for flu and strep throat, among other minor ailments. Since 2000, student pharmacists nationwide have received training to conduct CLIA-waived tests for minor ailments and infectious diseases, which are similar to the COVID-19 tests authorized under the Food and Drug Administration's (FDA) Emergency Use Authorization. Further, students have also been trained to interpret and communicate test results, all of which have been required competencies for PharmD candidates per the accreditation board's standards. By lifting this antiquated and unnecessary lab requirement, you will open the door for Pennsylvania's community pharmacies and their well-trained pharmacists to support your goal of increased COVID-19 testing.

Pharmacies and their trained pharmacists offer convenient access and well-trusted testing destinations. Pharmacies are within 5 miles of nearly 90% of Americans, including those in underserved urban and rural areas, where the presence of other healthcare providers is lacking. Further, patients benefit from increased access, with expanded hours that extend beyond when traditional providers are open.

A poll conducted by Morning Consult and commissioned by NACDS found that:

- 85% of Pennsylvania voters say it is easy to access pharmacies.
- 76% of Pennsylvania voters support pharmacist testing for COVID-19.

Additionally, and critically during a pandemic such as this, pharmacy-based testing models also reduce strain on other healthcare settings, such as clinics and emergency rooms. Pharmacies are well-positioned to assist with public health surveillance, as they already comply with data reporting requirements by state, local, and federal mandates.

Pennsylvania should join the 37 states that expressly allow pharmacy COVID-19 testing by removing the remaining barriers to clear the way for pharmacists and pharmacies to rapidly scale up testing to meet public health needs. The most effective and thorough way to authorize pharmacies to provide testing would be through an Executive or Emergency Order that waives any rules or restrictions that would in any way impede pharmacies or pharmacists from providing any aspect of end-to-end COVID-19 testing, to include, but not be limited to the laboratory employment experience requirement in the Pennsylvania Clinical Laboratory Act (Sept 26, 1951, PL 1539, No. 389). This would then allow any pharmacist or pharmacy that qualifies for federal authorization to perform CLIA-waived tests, including FDA-authorized COVID-19 tests, to do so in the Commonwealth.

Additionally, as Pennsylvania looks to the future in the fight against COVID-19, we urge you to proactively authorize pharmacists to initiate treatment as recommended by the Centers for Disease Control and Prevention (CDC) and take the requisite actions to authorize pharmacists to provide COVID-19 pandemic vaccine to people of all ages when appropriate. Pharmacist-administered vaccine aligns with the CDC's pandemic plans that rely on pharmacies to scale the direct distribution of forthcoming vaccines. Your action today would accelerate access to treatment and vaccine to the residents of your state.

These vital actions will allow the commonwealth to leverage the 8,600 trained pharmacists, providing critical support to your efforts to safely reopen Pennsylvania. Thank you for all your actions to protect the health of all the citizens of the Commonwealth. We look forward to partnering with you in this effort.

Sincerely,

Pennsylvania Pharmacists Association

Pennsylvania Association of Chain Drug Stores

Independent Pharmacy Buying Group

Independent Pharmacy Cooperative

Philadelphia Association of Retail Druggists

Keystone Pharmacy Purchasing Alliance, Inc.

Value Drug Company

American Pharmacists Association

American Society of Consultant Pharmacists

National Association of Chain Drug Stores

National Community Pharmacist Association

National Alliance of State Pharmacy Associations

Cc: The Honorable John Fetterman, Lt. Governor, Chair
Pennsylvania COVID-19 Response Task Force on Health Disparity