

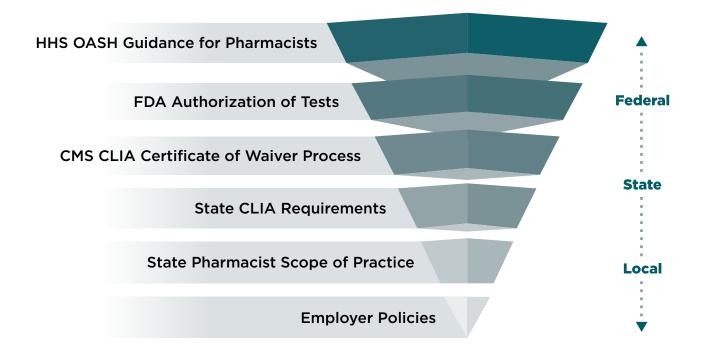
# **Authority to Test for COVID-19**

### **Pharmacists, Pharmacy Technicians, and Pharmacy Interns**

Pharmacists, pharmacy interns, and technicians are authorized by the federal government to conduct COVID-19 testing, subject to certain requirements, during the public health emergency. Learn about this temporary authority and the requirements that need to be met.

## **Pharmacists' Authority to Test for COVID-19**

In April 2020, the U.S. Department of Health and Human Services (HHS) Office of the Assistant Secretary for Health (OASH) <u>authorized licensed pharmacists</u> to order and administer FDA-authorized COVID-19 tests during the public health emergency under the Public Readiness and Emergency Preparedness (PREP) Act. In an <u>Advisory Opinion</u> that followed, HHS asserts this temporary authority was meant to preempt any state or local requirement that directly or indirectly prohibits a pharmacist from ordering or administering COVID-19 tests. Many entities are involved in supporting or impacting a pharmacist's ability to provide COVID-19 testing to patients, as depicted in the diagram below. More information about these entities follows.



### FDA Emergency Use Authorization of Point-of-Care Tests

Pharmacists' authority to order and administer COVID-19 tests requires that the test be authorized or cleared by the FDA. FDA authorization of COVID-19 tests is provided through <a href="Emergency Use Authorizations"><u>Emergency Use Authorizations</u></a> (EUAs). Pharmacists should refer to FDA's <a href="Eist of COVID-19"><u>list of COVID-19 tests with EUAs</u></a> before ordering a test.

## Authority to Test for COVID-19 (continued)



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It is also important to pay attention to the setting the test is authorized to be used in. Many tests are only authorized to be conducted in a high or moderate complexity laboratory; however, pharmacists can partner with these laboratories to collect the specimen from patients for these tests. In a point-of-care testing model, tests authorized for patient care settings (indicated by a "W" on FDA's list of COVID-19 tests with EUAs) can be conducted at pharmacies with an appropriate Clinical Laboratory Improvement Amendment (CLIA) Certificate of Waiver. "Pharmacy Models for COVID-19," in APhA's COVID-19 Resources: Know the Facts library, provides more information to help you understand the different approaches to testing and determine which model makes sense for your pharmacy practice.

For more information, refer to "Pharmacists' Guide to Authorized COVID-19 Tests and the CLIA Waiver Process" in APhA's COVID-19 Resources: Know the Facts library.

#### CMS CLIA Certificate of Waiver Process

CMS manages the process to obtain a CLIA Certificate of Waiver, and some states have additional regulations or guidance related to the process. CMS's <u>Quick Start Guide</u> details the process and includes helpful graphics and links. More information is also available on the agency's <u>CLIA webpage</u> as well as in its How to Obtain a CLIA Certificate of Waiver resource.

For more information, refer to "Pharmacists' Guide to Authorized COVID-19 Tests and the CLIA Waiver Process" in APhA's <u>COVID-19 Resources: Know the Facts</u> library.

#### State CLIA Requirements

Contact your <u>State Agency and CLIA Operations Branch</u> for state-specific considerations and requirements that may apply.

#### State Pharmacist Scope of Practice

Pharmacists interested in providing COVID-19 testing should refer to their <u>board of pharmacy</u> to identify state-based considerations or restrictions to testing provided by pharmacists and can reference the <u>National Alliance of State Pharmacy Associations (NASPA) COVID-19</u> <u>Testing</u> webpage to view information about state actions related to testing.

#### **Employer Policies**

Pharmacists should refer to employer policies to be familiar with requirements specific to their pharmacy practice setting.



## Authority to Test for COVID-19 (continued)



## **Pharmacists, Pharmacy Technicians, and Pharmacy Interns**

### Pharmacy Intern and Technician Authority to Test for COVID-19

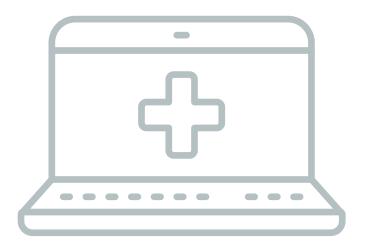
In October 2020, OASH issued <u>guidance</u> authorizing qualified pharmacy technicians and state-authorized pharmacy interns to administer FDA-approved COVID-19 tests, including serology tests, under the PREP Act during the public health emergency. Only pharmacists can order the test. The information below defines qualified state-authorized pharmacy interns and pharmacy technicians. Check the guidance for the specific requirements that are attached to this authority for interns and technicians.

#### State-Authorized Pharmacy Intern ("Intern")

- Pharmacy interns working in states with licensure and/or registration requirements must be licensed and/or registered in accordance with state requirements.
- Pharmacy interns working in states without licensure and/or registration requirements must be authorized by the state—or board of pharmacy in the state—in which the practical pharmacy internship occurs.

### **Qualified Pharmacy Technician ("Technician")**

- Pharmacy technicians working in states with licensure and/or registration requirements must be licensed and/or registered in accordance with state requirements.
- Pharmacy technicians working in states without licensure and/or registration requirements must have a Certified Pharmacy Technician (CPhT) certification from either the Pharmacy Technician Certification Board or the National Healthcareer Association.



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