Pharmacists’ Authority to Test for COVID-19

Many entities are involved in determining a pharmacist’s ability to order and administer tests in the COVID-19 pandemic. Pharmacists’ authority to order and administer tests is determined by state scope or practice and may be supported or limited by regulations and policies that are in place with each of those entities. This resource answers questions about authority from the federal level to the state level. Pharmacists are encouraged to familiarize themselves with their specific state and local entities that could support or limit pharmacists’ authority to order and administer COVID-19 tests.

Can pharmacists order and administer tests?

On April 8, 2020, the U.S. Department of Health and Human Services (HHS) Office of the Assistant Secretary for Health (OASH) released Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity under the PREP Act, which authorized “licensed pharmacists to order and administer COVID-19 tests, including serology tests, that the Food and Drug Administration (FDA) has authorized.” The guidance also noted that pharmacists ordering and administering tests pharmacists “will qualify as ‘covered persons’ under the PREP Act,” which provides liability immunity for any loss related to countermeasures to COVID-19. The guidance did not address state scope of practice considerations, the need for pharmacies to have CLIA Certificates of Waiver, payment for services, and many other factors that could facilitate or limit pharmacists’ ability to order and administer tests for COVID-19.
HHS then released an Advisory Opinion that confirms the Administration’s intent and confidence in pharmacists to order and administer COVID-19 tests. HHS is clear that this guidance preempts any state or local requirement that directly or indirectly prohibits a pharmacist from ordering or administering COVID-19 tests; however, pharmacists will still need to obtain a CLIA Certificate of Waiver and may need to meet additional state requirements to conduct CLIA-waived tests.

APhA is advocating and collaborating with key decision makers to gain clarity on the many factors that will affect pharmacists’ ability to order and administer tests. Pharmacists’ need to be reimbursed for COVID-19 testing and testing-related services they will provide, such as assessment of symptoms, specimen collection, and counseling patients.

**Which tests for SARS-CoV-2 are pharmacists authorized to order and administer?**

HHS’s guidance indicates that “licensed pharmacists can order and administer COVID-19 tests, including serology tests, that the Food and Drug Administration (FDA) has authorized.” FDA authorization is provided through Emergency Use Authorizations (EUAs), meaning HHS’s guidance only applies to tests with EUAs. The HHS guidance states that pharmacists may **order** any test that has an EUA. However, each EUA specifies the setting(s) where tests can be **administered**, and to date, most are only authorized for high- and moderate-complexity laboratories. The FDA’s [list of tests with EUAs](https://www.fda.gov/emergency-preparedness-and-response/coronavirus-2019) provides links to each test’s Letter of Authorization, which contains the section “Authorized Laboratories and Other Authorized Testing Locations.” This section must have “patient care settings” listed or otherwise authorize the test for use at the point-of-care for pharmacists to be able to administer the test outside of the clinical laboratory environment. Point-of-care tests are indicated on the FDA’s list of tests with EUAs, under the “Authorized Setting” category with a “W”. Refer to APhA’s [Demystifying COVID-19 Testing](https://www.pharmacist.com) resource to learn more about types of COVID-19 tests and how they are authorized.

**Are pharmacists’ practice sites required to have CLIA Certificates of Waiver for the pharmacist to administer tests for SARS-CoV-2?**

It depends on the type of pharmacy testing model. If the “Authorized Laboratories and Other Authorized Testing Locations” section of a point-of-care test’s EUA indicates “patient care settings,” that test is **considered to be CLIA waived** for the duration of the emergency declaration, meaning any patient care setting where the test is administered must have a CLIA Certificate of Waiver or Certificates of CLIA Compliance. Pharmacists can partner with a CLIA-certified high or moderate complexity laboratories to collect respiratory specimens for FDA EUA COVID-19 tests. If a pharmacy chooses this type of testing model, the pharmacy will not need a CLIA Certificate of Waiver to collect specimens on behalf of the certified laboratory. Pharmacists can also work with a physician or other practitioner to provide assessment and specimen collection services. APhA’s [Pharmacy Models for COVID-19 Testing](https://www.pharmacist.com) resource provides an overview of the necessary steps a pharmacy must take to provide COVID-19 testing either in partnership with a laboratory or at the point of care, including [How to Obtain a CLIA Certificate of Waiver](https://www.pharmacist.com). For more information about the CLIA Certificate of Waiver, see APhA’s [COVID-19 Testing Basics](https://www.pharmacist.com).
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How do states’ scope of practice laws affect pharmacists’ ability to order and administer tests for SARS-CoV-2, as authorized by HHS’ guidance?

Pharmacists may not be permitted to order, interpret, collect specimens, or administer laboratory tests under their state’s pharmacy practice act. Pharmacists interested in providing COVID-19 testing should refer to their board of pharmacy to identify state-based considerations or restrictions to testing provided by pharmacists and can reference the National Alliance of State Pharmacy Associations (NASPA) COVID-19 Testing webpage to view information about state actions related to testing.

Many states require a collaborative practice agreement with a prescriber(s) that specifically delegates these additional responsibilities to a pharmacist or group of pharmacists. The appendices of the CDC’s Advancing Team-Based Care Through Collaborative Practice Agreements (CPA) provide a full analysis of state CPA laws, including whether CPAs may include delegated authority for pharmacists to order, interpret, and perform laboratory tests. Note that this resource was published in 2017, and state CPA laws may have been updated since publication. Many states are considering executive actions and orders that may provide broader authority for pharmacists to order and administer tests. NASPA maintains a current list of relevant executive orders and actions.

What are some key questions needing clarification as APhA advocates for pharmacists’ best interests?

APhA is collaborating closely with federal agencies and other pharmacy stakeholders to inform and request future guidance related to pharmacists’ role in COVID-19 testing. A sampling of the key questions that need clarification are:

- When state scopes of practice are more restrictive than the HHS guidance related to pharmacist authority to order or administer tests, will pharmacists be limited by the state scope of practice until a state-level executive action or order to expand authority?
- How will pharmacists be compensated under Medicare for ordering and/or administering tests and the associated testing-services such as assessment of symptoms, specimen collection, and counseling patients for SARS-CoV-2?
- How will pharmacists be compensated under Medicaid by the states for ordering and/or administering tests for SARS-CoV-2?
- What will pharmacists need to do to be compensated by private payers for ordering and/or administering tests for SARS-CoV-2?
- What billing codes should pharmacists use to bill for testing services? Are those codes different depending on the type of test (e.g., serologic, saliva)?
- Do pharmacists need a formal “order” to administer COVID-19 tests?
- Will there be an accelerated path to obtaining a CLIA Certificate of Waiver for pharmacies that want to provide testing?

Answers to these questions and additional information will be shared as they become available.

Disclaimer: Information related to the COVID-19 pandemic is changing rapidly and continuously. The material and information contained in this publication is believed to be current as of the date included on this document. The American Pharmacists Association assumes no responsibility for the accuracy, timeliness, errors, or omission contained herein. Links to any sources do not constitute any endorsement of, validity, or warranty of the information contained on any site. The user of these materials should not under any circumstances solely rely on, or act based on this publication. Pharmacy professionals retain the responsibility for using their own professional judgement and practicing in accordance with all rules, regulations, and laws governing the pharmacy practice within their jurisdiction.