Guidance

U.S. Department of Health & Human Services
Office of the Assistant Secretary for Health
Wednesday, April 8, 2020

Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity under the PREP Act

On January 31, 2020, the Secretary of Health and Human Services declared that the 2019 novel coronavirus (COVID-19) is a public-health emergency for the United States. The United States Department of Health and Human Services (HHS) is the lead agency for the federal government's response to the COVID-19 pandemic.

A key component of that response is rapidly expanding COVID-19 testing across America. Within HHS, the Office of the Assistant Secretary for Health leads federal efforts to support that expansion.

Pharmacists, in partnership with other healthcare providers, are well positioned to aid COVID-19 testing expansion. Pharmacists are trusted healthcare professionals with established relationships with their patients. The vast majority of Americans live close to a retail or independent community-based pharmacy. That proximity reduces travel to testing locations, which is an important mitigation measure. Pharmacists also have strong relationships with medical providers and hospitals to appropriately refer patients when necessary.

Therefore, as an Authority Having Jurisdiction under the Secretary's March 10, 2020 declaration under the Public Readiness and Emergency Preparedness Act (PREP Act), OASH issues this guidance authorizing licensed pharmacists to order and administer COVID-19 tests, including serology tests, that the Food and Drug Administration (FDA) has authorized. *See* 85 Fed. Reg. 15,198, 15,202 (March 17, 2020); *see also* Pub. L. No. 109-148, Public Health Service Act § 319F-3, 42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e.[1] By doing so, such pharmacists will qualify as "covered persons" under the PREP Act. And they may receive immunity under the PREP Act with respect to all claims for loss caused by, arising out of, relating to, or resulting from, the administration or use of FDA-authorized COVID-19 tests. 42 U.S.C. § 247d-6d(a)(1).

[1] FDA's Emergency Use Authorizations for diagnostic and therapeutic medical devices to diagnose and respond to particular public health emergencies are available here.

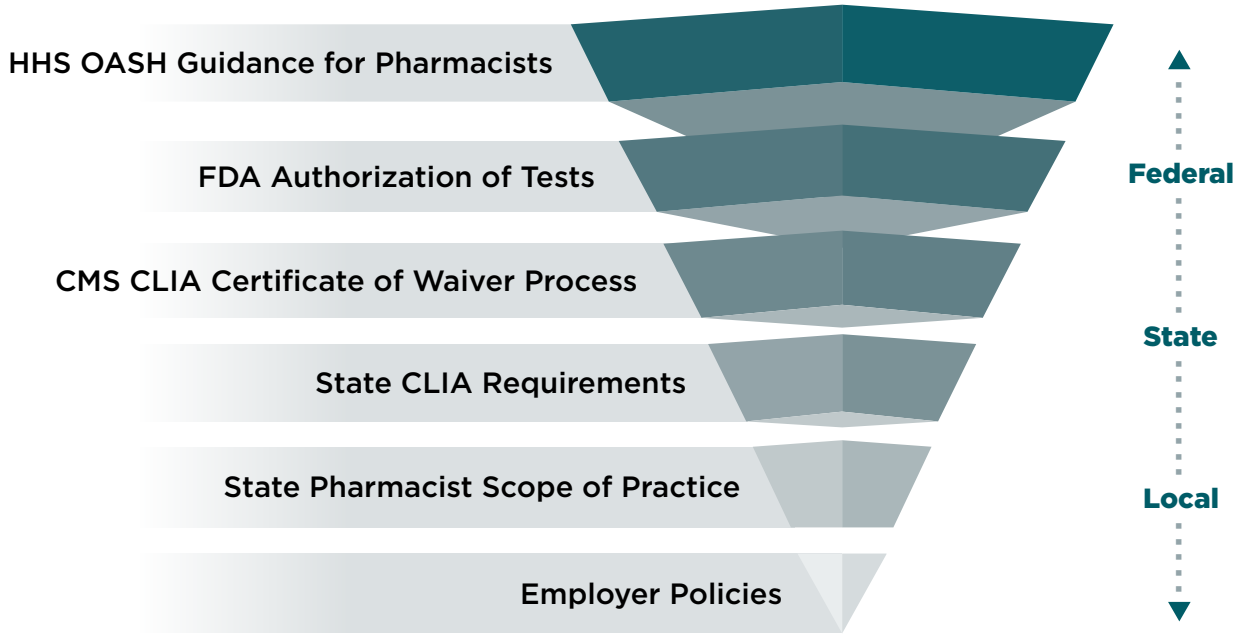
[2] This guidance does not speak to or change reimbursement policy whether a licensed pharmacist may obtain reimbursement from a government or private payer for ordering or administering an FDA-authorized test.

Pharmacists' Authority to Test for COVID-19

Understanding HHS Guidance on Pharmacists' Authorization to Order and Administer Tests for the SARS-CoV-2 Virus

On April 8, 2020, the U.S. Department of Health and Human Services (HHS) Office of the Assistant Secretary for Health (OASH) released guidance authorizing pharmacists to order and administer certain tests authorized by the Food and Drug Administration (FDA) for COVID-19. This guidance further solidifies pharmacists' official role as front-line responders in the COVID-19 pandemic. Many questions have emerged based on this guidance, and APhA is collaborating with pharmacy and government stakeholders to advocate for pharmacists and clarify questions resulting from the guidance.

Many entities are involved in determining a pharmacist's authority to order and administer tests in the COVID-19 pandemic. Pharmacists' authority to order and administer tests may be supported or limited by regulations and policies that are in place with each of those entities. This resource answers questions 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.



Additionally, this resource does not address payment for pharmacist-ordered or -administered tests. The HHS OASH guidance provides a footnote that states, "This guidance does not speak to or change reimbursement policy of whether a licensed pharmacist may obtain reimbursement from a government or private payer for ordering or administering an FDA-authorized test." APhA is advocating for and collaborating with relevant stakeholders to promote pharmacists' need to be reimbursed for the testing services they will provide.

Pharmacists' Authority to Test for COVID-19 (continued)

Understanding HHS Guidance on Pharmacists' Authorization to Order and Administer Tests for the SARS-CoV-2 Virus

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 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.

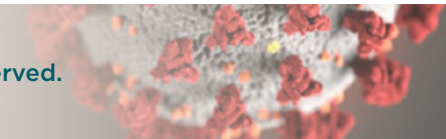
Can pharmacists administer serology tests for SARS-CoV-2 that do not have EUAs?

HHS's guidance also indicates licensed pharmacists can order and administer serology tests that FDA has authorized. Considering that serology tests are less complex than molecular tests and are solely used to identify antibodies to the virus, the FDA, under the Policy for Diagnostic Tests for Coronavirus Disease-2019, is allowing development and distribution of serology tests without going through the EUA process. However, such serology tests to identify antibodies to SARS-CoV-2 must be validated, the FDA must be notified of the validation, and the testing reports must include a specific statement that the test "has not been reviewed by the FDA." These serology tests that do not have EUAs are not considered to be authorized by FDA and, therefore, cannot be administered by pharmacists under the HHS OASH guidance.

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

Yes. 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.

The Centers for Medicare and Medicaid Services (CMS) How to Obtain a CLIA Certificate of Waiver details the process and includes FAQs and helpful links to state agencies. It is important to check each state's pharmacy practice act and other state guidance on CLIA for specific guidance on how pharmacies can be granted CLIA Certificates of Waiver.



Pharmacists' Authority to Test for COVID-19 (continued)

Understanding HHS Guidance on Pharmacists' Authorization to Order and Administer Tests for the SARS-CoV-2 Virus

How do states' scope of practice laws affect pharmacists' ability to order and administer tests for SARS-CoV-2, as authorized by HHS's guidance?

Pharmacists may not be permitted to order, interpret, or administer laboratory tests under their state's pharmacy practice act. 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. Under non-emergency conditions, many states require a collaborative practice agreement (CPA) 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 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.

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:

- How will pharmacists be compensated under Medicare for ordering and/or administering tests for SARS-CoV-2?
- How will pharmacists be compensated under Medicaid 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. 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 judgment and practicing in accordance with all rules, regulations, and laws governing the pharmacy practice within their jurisdiction.*