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COVID-19 TESTING BY PHARMACISTS

The Department of Health and Human Services, Office of the Assistant Secretary for Health (OASH), recently issued guidance authorizing licensed pharmacists to order and administer COVID-19 tests, including serology tests, that the Food and Drug Administration (FDA) has authorized.^{1,2} The South Carolina Board of Pharmacy offers the following information to assist its licensees in ordering and administering FDA-authorized COVID-19 tests.³

Who Can Perform Testing?

Pharmacists may perform FDA-authorized COVID-19 tests⁴ at any location that meets the applicable requirements under state and federal law.

CLIA Certificate

All sites where a pharmacist performs FDA-authorized COVID-19 testing must have a CLIA certificate for the appropriate type of testing that will be performed. For more information on obtaining a CLIA certificate visit:

- SC DHEC CLIA Program⁵
- Center for Medicare and Medicaid Services

Point-of-Care Testing

The U.S. Food and Drug Administration (FDA) recently clarified that, when it grants an Emergency Use Authorization (EUA) for a point-of-care test, that test is deemed to be CLIA-waived.⁶

For purposes of the OASH guidance, point-of-care testing that is authorized under an EUA does not require a prescriber's order prior to administration because it is deemed CLIA-waived. Tests that are indicated with a "W" under the "Authorized Setting(s)" section of the list of "In Vitro Diagnostics EUAs" on the FDA website⁷ are considered CLIA-waived point-of-care tests.

¹ <https://www.hhs.gov/sites/default/files/authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.pdf>

² A list of FDA-approved tests is available at: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations# covid19ivd>

³ To the extent any information contained herein is different from, or is in conflict with, any requirement applicable under federal law as contemplated by 42 U.S.C.A. § 247d-6d(8)(a), the requirement applicable under federal law shall apply.

⁴ See footnote 2.

⁵ <https://www.scdhec.gov/health-regulation/health-facility-regulations-licensing-con/medicaid-medicare-certification/clia-0>

⁶ https://www.cdc.gov/csels/dls/locs/2020/fda_clarifies_clia-waived_status.html

⁷ See footnote 2.

Training

All pharmacists conducting COVID-19 must receive appropriate training to conduct testing in a safe and effective manner and must adhere to the manufacturer's instructions for administering tests. This provision applies to testing conducted at pharmacies as well as pharmacies that use employees to conduct testing off-site (for example, partnering with a hospital or third-party laboratory).

PPE and Infection Control

All COVID-19 testing must be conducted by staff wearing appropriate PPE, including face masks and gloves. Additionally, all testing areas must be regularly disinfected. The CDC has issued Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19).⁸ These guidelines include the following:

For providers collecting specimens or within 6 feet of patients suspected to be infected with SARS-CoV-2, maintain proper infection control and use recommended personal protective equipment, which includes an N95 or higher-level respirator (or facemask if a respirator is not available), eye protection, gloves, and a gown, when collecting specimens.

For providers who are handling specimens, but are not directly involved in collection (e.g. self-collection) and not working within 6 feet of the patient, follow Standard Precautions; gloves are recommended. Healthcare personnel are recommended to wear a form of source control (facemask or cloth face covering) at all times while in the healthcare facility.

Additionally, Pharmacists are encouraged to review the CDC's Information for Healthcare Professionals about Coronavirus (COVID-19).⁹

Billing and Reimbursement

As the Board has no jurisdiction over third-party-payors, it cannot offer any guidance on reimbursement for COVID-19 testing administered by pharmacists.

⁸ <https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html>

⁹ <https://www.cdc.gov/coronavirus/2019-nCoV/hcp/index.html>