Kentucky Statewide Physician Protocol for Point of Care COVID-19 Testing

Purpose

This statewide physician protocol signed by a physician with the Kentucky Department for Medicaid Services specifies the criteria and procedures for eligible pharmacies who have met the requirements established by the Kentucky Board of Pharmacy and in accordance with the Governor's Executive Order to prevent the spread of COVID-19 in the Commonwealth. *This signed protocol is intended for pharmacists that **do not** have a medical provider to issue a protocol.*

Point of Care COVID-19 Testing Protocol	
Pharmacy has an active CLIA Certificate of Waiver	• Pharmacist collects specimen or aids in self-collection of the specimen; specimen is tested by the pharmacy using a point-of-care test • The Kentucky Office of the Inspector General Division of Health Care processes CLIA applications. Additional information can be found here. • Testing and or collection site pharmacies should reach out to the Kentucky Department for Public Health to be added to the Kentucky COVID-19 testing facility list.

Testing Supplies	• Pharmacy obtains point-of-care testing machine and testing cassettes
	  ○ These tests that can be administered in a CLIA waived setting, found here on the FDA website
	  ○ Point-of-care identified as a test with a "W" under "Authorized Settings," will be allowed during the state of emergency
	• Pharmacy has obtained specimen collection kits
	• Pharmacy employees have received training on testing machine

Personal Protective Equipment	• CDC Infection Control Guidance for Healthcare Professional about COVID-19 has been reviewed • CDC Collecting, Handling, and Testing Clinical Specimen from Persons for COVID-19 Interim Guidelines have been reviewed • Pharmacy obtains adequate PPE • All pharmacy employees have been trained on minimum storage, disposal/recycling, and use of PPE including fit testing prior to using N-95 respirators
Specimen Collection	• CDC Collecting, Handling, and Testing Clinical Specimen from Persons for COVID-19 Interim Guidelines have been reviewed • Pharmacy has reviewed manufacturer instructions • Pharmacy employees are trained on the type of specimen collection • Policies and procedures are in place to address collection, storage and transport of samples ○ Collection is encouraged to take place outside in order to minimize exposure to others in the pharmacy • Pharmacy has identified a proper method of disposal of specimens and any PPE that may have been in contact with patient
Communication of Results	• CDC Clinical Guidance for Management of Patients with Confirmed COVID-19 has been reviewed • Pharmacies develop policies and procedures for reporting results to the patient and the patient's primary care provider including test results within the same day • Pharmacy has the responsibility to inform the patient of results conducted at point-of-care • Ensure patient has a mask or provide the patient with a mask • Pharmacy must report all positive COVID-19 tests to the Kentucky Department for Public Health via the Person Under Investigation (PUI) Report form

	• Pharmacy must report all positive COVID-19 tests to the Kentucky Department for Public Health via the Kentucky Reportable Disease form
Reimbursement	• Pharmacies must enroll as a DME provider • Pharmacies can then bill using their existing NPI on a CMS 1500 or 837 P electronic form • Pharmacies should have a standing order from a licensed and enrolled Medicaid provider for COVID-19 testing ○ This document will serve as the standing order for the Kentucky Medicaid Medical Director. • Current HCPCS codes of U0002 and CPT 87635 should be billed to Medicaid for COVID-19 testing

COVID-19 Antigen Testing Statewide Physician Protocol Signatures:

Judith Ann Theriot, MD (electronic signature) August 3, 2020

Judith Ann Theriot, MD
Medical Director
Kentucky Department Medicaid Services
National Provider ID: 1811990476

Date Signed