COVID-19 Molecular Testing Pharmacy Checklist

Purpose

On April 8, 2020, the U.S. Department of Health and Human Services (HHS) published guidance under the Public Readiness and Emergency Preparedness (PREP) Act authorizing licensed pharmacists to order and administer FDA-authorized COVID-19 tests for the duration of the national public-health emergency. The below information is intended to clarify the steps pharmacies must take to ensure accurate testing and employee safety.
Pursuant to Executive Order 01-20, the Commissioner of Health and the Secretary of State authorize Vermont pharmacists to order and administer COVID-19 tests approved by FDA and the Vermont Department of Health for pharmacy-based sample collection or administration.

Models

- Model 1: Pharmacist collects specimen or aids in self-collection of the specimen; specimen is sent to a laboratory for testing.
- Model 2: Pharmacist collects specimen or aids in self-collection of the specimen; specimen is tested by the pharmacy using a point-of-care test.

Checklist

Testing Services	
Model 1	**Model 2**
☐ **Pharmacy has contracted with a laboratory for testing.** *List of laboratories with which pharmacies may contract for testing of specimens from Vermont residents email Vermont Department of Health (the Health Department) at AHS.VDHELRSupport@vermont.gov.*	☐ **Pharmacy has an active CLIA-Waiver number.** *The NH Department of Health and Human Services processes CLIA applications for any new Certificate of Waiver requests. First step is to email Aaron Doyle. Information on the waiver application process can be found here.*

Testing Supplies	
Model 1	**Model 2**
☐ **Pharmacy has obtained specimen collection kits including specimen swabs and viral transport media.** *Pharmacy will need to obtain supplies; contracted lab may be able to assist.*	☐ **Pharmacy has obtained point-of-care testing machine and testing cassettes.** *FDA website lists testing devices; Test with a "W" in the "Authorized Settings" column is a CLIA waived tests and can be performed in a patient care/pharmacy setting during the declared emergency.* ☐ **Pharmacy has obtained specimen collection kits.** *Pharmacy will need to obtain specimen collection kits* ☐ **Pharmacy employees have been trained on testing machine.**

Personal Protective Equipment (PPE)
Both Models
☐ **CDC Infection Prevention Guidelines have been reviewed.** ☐ **CDC Specimen Collection, Handling, and Testing Guidelines have been reviewed with emphasis on PPE required depending on type of specimen collection occurring.** ☐ **Pharmacy has obtained adequate PPE.** *The pharmacy will need to supply their own PPE.* ☐ **Pharmacy employees have been trained.** *Training should include at a minimum storage, disposal/recycling, and use of PPE, including fit testing prior to using, if N-95 respirators are employed.*

Specimen Collection	
Model 1	**Model 2**
☐ **CDC Specimen Collection Guidelines have been reviewed.** ☐ **Pharmacy has received guidance from contracted laboratory on accepted specimen type.** *Patient-collected nasal swabs would be preferred as it limits potential exposures and required PPE.* ☐ **Pharmacy employees are trained on the type of specimen collection.** ☐ **Pharmacy has identified a location to collect specimens and has planned the logistics.** *Specimen collection shall take place outside via drive-up window or in a parking lot 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.**	☐ **CDC Specimen Collection Guidelines have been reviewed.** ☐ **Pharmacy has reviewed manufacture instructions and will abide by the procedures.** *Patient-collected nasal swabs would be preferred as it limits potential exposures and required PPE.* ☐ **Pharmacy employees are trained on the type of specimen collection.** ☐ **Pharmacy has identified a location to collect specimens and has planned the logistics**. *Specimen collection should take place outside in an open space (e.g., parking lot) 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
Both Models
☐ **Pharmacy has process in place to notify patient and primary care provider (if applicable) of results.** ☐ **Pharmacy has process in place to refer positive patients to their primary care provider.** **See script from Health Department for example of how to report results to a patient.**

Reporting Results to the Health Department Vermont Health Information Exchange (VHIE)	
Model 1	**Model 2**
☐ **Pharmacy has confirmed laboratory will be reporting all results to the Health Department as required by the Reportable and Communicable Diseases Rule, CVR 13-140-007**	☐ **Upon receipt of its CLIA-waiver number, the pharmacy contacted the Health Department by emailing AHS.VDHELRSupport@vermont.gov with its intention to perform tests and set up electronic reporting capabilities with VHIE**