Iowa Board of Pharmacy

ANDREW FUNK, PHARM.D.
EXECUTIVE DIRECTOR

April 23, 2020

On January 31, 2020, pursuant to Section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency due to the novel coronavirus which causes Coronavirus Disease-2019 (COVID-19). Pursuant to the Public Readiness and Emergency Preparedness Act (PREP Act) and Guidance issued by the United States Department of Health and Human Services, Office of the Assistant Secretary for Health on April 8, 2020, ***licensed pharmacists are authorized to "order and administer COVID-19 tests, including serology tests, that the Food and Drug Administration (FDA) has authorized***." The authority of pharmacists to order and administer COVID-19 tests extends only through the federal government's designation of the public health disaster. Pharmacist administration of COVID-19 testing beyond the federal public health disaster must be pursuant to an order by a licensed health care practitioner who is authorized to prescribe.

The Board provides this Guidance for pharmacists who engage in COVID-19 testing.

TYPES OF TESTS WHICH CAN BE ORDERED AND ADMINISTERED BY PHARMACISTS

The HHS Guidance authorizes pharmacists to order and administer COVID tests *which are authorized by FDA*. The pharmacist must ensure that the test to be administered is authorized by FDA either under a normal approval process or through the FDA's Emergency Use Authorization process. *Pharmacists are not authorized to order and administer a COVID-19 test which has not received FDA authorization, even if it may be available in the marketplace.*

- *Diagnostic COVID-19 Testing at the Point-of-Care / Patient Care Setting (Pharmacy)*

There are currently three diagnostic tests authorized by FDA to be used at the point-of-care: Abbott ID NOW, GeneXpert Xpert Xpress, and Accula. The Abbott and GeneXpert tests require a nasal swab while the Accula test requires both a nasal and throat swab.

- *Diagnostic COVID-19 Testing at Laboratory with Specimen Collection at Pharmacy*

There are currently many diagnostic tests authorized by FDA to be processed by a moderate or high-complexity CLIA laboratory. The pharmacy would collect the patient's respiratory specimen at the pharmacy (the type of respiratory specimen collected would be determined by the test kit to be used and could include a simple nasal swab or more invasive nasopharyngeal swab) and send the specimen to a moderate or high-complexity laboratory for testing (the complexity of the lab would be determined by the test kit to be used).

- *Diagnostic COVID-19 Testing at Laboratory with Specimen Collection at Patient's Home*

There is currently one diagnostic test authorized by FDA to be processed by LabCorp (Pixel by LabCorp COVID-19 Test) which uses a nasal swab specimen collected by the patient at their home. The nasal swab specimen is packaged and mailed to LabCorp for analysis. A patient may only obtain this at-home diagnostic test kit with an order by a practitioner, including a pharmacist.

- *Serologic COVID-19 Testing at the Point-of-Care / Patient Care Setting (Pharmacy)*

There are currently no COVID-19 serology tests authorized by FDA to be used at the point-of-care. It should be noted that, even when a serology test may be authorized by FDA for POC use, the Iowa Department of Public Health cautions against using tests that simply require a finger stick specimen in the absence of rigorous testing to ensure the tests are accurate and reliable in their results.

- *Serologic COVID-19 Testing at Laboratory with Specimen Collection at Pharmacy*

There are currently four COVID-19 serology tests authorized by FDA to be processed by a moderate or high-complexity CLIA laboratory. The pharmacy would collect the patient's blood specimen at the pharmacy (the type of blood specimen collected would be determined by the test kit to be used and could include a simple finger stick or more invasive venipuncture procedure) and send the specimen to a moderate or high-complexity laboratory for testing (the complexity of the lab would be determined by the test kit to be used). It should be noted that the Iowa Department of Public Health cautions against using tests that simply require a finger stick specimen in the absence of rigorous testing to ensure the tests are accurate and reliable in their results.

LABORATORY INFORMATION

- *Point-of-care testing (POCT)*: If a pharmacy intends to order and administer POCT, it must first have a current CLIA Certificate of Waiver to conduct CLIA-waived tests, such as POCT for COVID-19. A pharmacy that does not have a CLIA Certificate of Waiver may complete the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (CMS Form 116) and submit to the:

  Iowa CLIA Laboratory Program
  State Hygienic Laboratory
  University of Iowa Research Park
  2490 Crosspark Road
  Coralville, IA 52241
  (319) 335-4500 or (800) 421-IOWA
  FAX: (319) 335-4174
  Email: shl.clia@uiowa.edu

On the application for a CLIA Certificate of Waiver, the pharmacy may be required to identify the specific CLIA-waived test(s) intended to be administered at the pharmacy.

- *Moderate or High-Complexity testing*: Pharmacy collection of patient specimens (respiratory for diagnostic, venous blood for serologic) for subsequent moderate or high-complexity lab analysis must identify and coordinate with a laboratory for such testing. No CLIA Certificate of Compliance or Waiver is required for specimen collection. Possible laboratory options may include, but cannot be guaranteed by the Board:
    - Quest Diagnostics
    - ARUP
    - LabCorp
    - State Hygienic Lab

POLICIES AND PROCEDURES

The pharmacy must ensure that, depending on the test(s) to be conducted, a complete policy and procedure is established and followed which includes but is not limited to:

- Notification of the pharmacy's intent to order and administer COVID-19 tests via updating the pharmacy's online profile with the Board via View User Profile and Update Demographics to identify "COVID-19 Diagnostic" or "COVID-19 Antibody" testing as an available pharmacy service;
- Notification to the test kit manufacturer and FDA (via email at CDRH-EUA-Reporting@fda.hhs.gov) of any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the test kit;
- Patient screening parameters prior to ordering and administering a test, including identification of testing priority groups;
- Personnel training required prior to engaging in specimen collection and testing, including review and understanding of the test kit manufacturer instructions / package insert;
- Strict adherence to the testing procedure identified in the test kit manufacturer instructions / package insert;
- Appropriate use of personal protective equipment (PPE);
- Environmental security measures that will be in place to prevent the spread or transmission of the coronavirus by a potentially infected individual presenting to the testing site;
- Evaluation of test results;
- Dissemination of test results to the patient, the patient's primary care practitioner, and the local public health agency; and
- Patient guidance to be provided based on the test type (diagnostic or serologic) and test result (positive or negative).

PERSONNEL TRAINING

Pharmacy personnel who will be conducting COVID-19 testing must be properly trained on the testing policy and procedures, proper specimen collection, proper use of personal protective equipment (PPE), and evaluation of test results prior to engaging in specimen collection and/or testing. Documentation of completed training, and documented observed competency for specimen collection and use of PPE, for each individual involved in specimen collection and/or testing must be maintained in the pharmacy and available for inspection and copying by the Board or its authorized representative.

SUPPLIES FOR COLLECTION OF PATIENT SPECIMENS

A pharmacy engaged in COVID-19 testing, either at POC or collection of specimens for moderate or high-complexity laboratory testing, which is having difficulty obtaining supplies for collecting patient specimens may call the FDA Hotline (1-888-INFO-FDA, option *) for assistance.

TEST RESULT REPORTING

A pharmacy engaged in COVID-19 testing (including at POC, collection of specimens for moderate or high-complexity laboratory testing, or ordering a test for a patient's at-home specimen collection and submission to a moderate or high-complexity laboratory) must provide all test results to the patient, the patient's primary care practitioner (if identified), and to the Iowa Department of Public Health (electronically through the Iowa Disease Surveillance System, preferred, or via fax to 515-281-5698).

The pharmacy must update the pharmacy's online profile with the Board via View User Profile and Update Demographics to identify the pharmacy's service(s) of "COVID-19 Diagnostic" and/or "COVID-19 Antibody" testing. Within approximately 48 hours, the pharmacy will receive via email a template to use for submission of test results to the IDSS. If the pharmacy has not received the template within 72 hours, please contact sue.mears@iowa.gov.

Mandatory reporting of all COVID-19 test results is pursuant to an order issued April 18, 2020 by Dr. Caitlin Pedati, IDPH Medical Director and State Epidemiologist, and extends through December 31, 2020.

TREATMENT FOLLOWING A POSITIVE COVID-19 TEST RESULT

Under current Iowa law, a pharmacist is not authorized to order and dispense any prescription medication in response to a positive diagnostic test for COVID-19 (or any other point-of-care test). A patient whose diagnostic test result is positive (or whose serologic IgM test result is positive) must be referred to a prescriber for further evaluation and possible treatment.

FINAL REMINDER

The information provided here is current as of April 23, 2020. A pharmacy engaged in COVID-19 testing must continue to be aware of current recommendations and authorizations for such testing. While the HHS Guidance issued April 8, 2020 provides pharmacists immunity from damages as a result of conducting COVID-19 countermeasures, the Board's expectation is that pharmacists are conducting these tests under strict policy and procedures and adhering to the test kit product insert.