CONNECTICUT DEPARTMENT OF **CONSUMER PROTECTION**

DRUG CONTROL DIVISION

May 8, 2020

Pharmacist Role in COVID-19 Testing FAQs

For the purposes of this document the term "administer" includes the process of instructing the patient, preparing the specimen collection site, choosing the appropriate collection technique, obtaining a valid specimen, assuring the patient's well being, the judicious handling, transporting and processing of the specimen, and reporting the results in a clear and concise manner to the practitioner whose order initiated the process

- **Can pharmacists order/administer COVID-19 tests?**
  - Connecticut statutes permit licensed pharmacists to administer COVID-19 tests, and *as of May 7, 2020, Governor Lamont's Executive Order 7KK allows pharmacists to order Food and Drug Administration (FDA) approved tests for COVID-19 for the duration of the public health and civil preparedness emergency, unless earlier modified, extended or terminated.*
  - Federally, the Clinical Laboratory Improvement Amendments (CLIA) require all entities that administer or order the administration of even one test, including waived tests, on "materials derived from the human body for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of human beings" to meet certain requirements. If an entity administers or orders the administration of tests for these purposes, it is considered under CLIA to be a laboratory and must register with the CLIA program. (see below for CLIA waiver process)
  - Although licensed pharmacists have been authorized by the Office of the Assistant Secretary for Health (OASH) under the Public Readiness and Emergency Preparedness Act (PREP Act) to order and administer COVID-19 tests, including serology tests, that the FDA has authorized, they would still need a CLIA registration.

- **Can pharmacy technicians and/or interns order COVID-19 tests?**
  No, however, they may participate in the collection of the sample and administration of the test after receiving adequate training.

- **Is there any specialized training/certification required to administer COVID-19 tests?**
  - No specific additional training/certification is required for pharmacists. Standard Operating Procedures (SOPs) for personnel training are to be determined by the

testing site and the pharmacist shall become familiar with all of the requirements of the test that they are administering.

- **Can pharmacists currently participating in collaborative drug therapy management agreements order a COVID-19 test, under that agreement?**
    - Pharmacists currently participating in a collaborative drug therapy management agreement would be able to order a COVID-19 test if it is permitted under the agreement. However, due to Executive Order 7KK a pharmacist is now permitted to order the COVID-19 test without a collaborative drug therapy management agreement.

- **What does a pharmacist need to administer a COVID-19 test?**
    - A pharmacist needs to issue a valid order or receive one from a physician, APRN, or PA.
    - Each location where testing is being administered must be registered as a CLIA-waived testing site and shall only utilize laboratory test kits that are FDA approved as waived complexity. (see directions below)

- **How do community pharmacies sign up to begin administering tests?**
    - Enroll as CLIA-waived testing site:
        - Complete CLIA application form CMS-116 and email to the Connecticut Department of Public Health (DPH) at DPH.FLISLab@ct.gov
        - Once the CMS-116 application has been completed and submitted with all required information a CLIA number will be assigned. Once the CLIA number has been assigned, the applicant can begin COVID-19 testing and training personnel if applicable CLIA requirements have been met (e.g., establishing performance specifications).
            - A helpful reference document can be found here.

    Note: applications for CLIA-waived testing sites administering COVID 19 tests are being expedited during this time.

- **How can I check to see if my location is already enrolled as a CLIA-waived testing site?**
    - Refer to this link to look up laboratory information such as type of CLIA certificate, date of expiration, etc.

- **What COVID-19 testing kits are available for pharmacy use?**
    - Pharmacists can administer COVID-19 oropharyngeal and nasopharyngeal swab, sputum and fingerstick testing kits that have been authorized for use by the FDA at CLIA waived testing sites.
    - Point of care (POC) tests that are deemed to be CLIA waived can be administered.
    - Refer to this link for a list of test kits that have received Emergency Use Authorization (EUA).

    This website will also provide the authorized setting for the test, authorization documents for the healthcare provider, patient fact sheet, and package insert (abbreviated as IFU).

- **Where can pharmacists obtain testing kits?**
  - Ordering and contact information can be found in the IFU document for the specific testing kit on the FDA website mentioned above.

- **What are the storage requirements for testing kits?**
  - Please refer to the IFU document for the specific testing kit on the FDA website mentioned above.

- **What information should pharmacists provide to patients upon administering the test?**
  - A fact sheet for patients is to be provided at time of testing. Approved fact sheets for each test can be found on the following website in the "Test Kit Manufacturers and Commercial Laboratories Table."

- **What is the typical turnaround time for the tests?**
  - Turnaround time can vary between type of tests. Please refer to the package insert for the testing kit.

- **What are the proper procedures for handling and disposing of COVID-19 tests once completed?**
  - Per the Centers for Disease Control and Prevention (CDC) guidelines use standard precautions including hand hygiene and the use of personal protective equipment (PPE) such as laboratory coats or gowns, gloves, and eye protections during point of care testing. In addition, the CDC recommends to "handle laboratory waste from testing suspected or confirmed COVID-19 patient specimens as all other biohazardous waste in the laboratory. Currently, there is no evidence to suggest that this laboratory waste needs any additional packaging or disinfection procedures."

- **Do pharmacists need to report results to a database?**
  - As with any facility administering a test for a reportable disease, results must be sent to the Connecticut DPH. To get further information on what is required please email DPH.ELR@ct.gov and DPH staff will get back to you.

- **What are some additional resources that are available to pharmacists?**
  - The CDC website has up-to-date information for both the general public and health care providers.
  - Additional guidance regarding CLIA laboratories issued by the Department of Health & Human Services Centers for Medicare & Medicaid Services.

Sources:

https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf

https://www.cms.gov/files/document/clia-laboratory-covid-19-emergency-frequently-asked-questions.pdf

https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS116.pdf

https://ncpa.org/point-care-poc-testing

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

https://www.cdc.gov/coronavirus/2019-ncov/downloads/COVID-19-Persons-Under-Investigation-and- Case-Report-Form-Instructions.pdf

https://www.cdc.gov/coronavirus/2019-ncov/downloads/pui-form.pdf

https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html

https://www.Cdc.gov/clia/docs/waived-tests/ready-set-test-booklet.pdf