PHARMACIST COVID-19 TESTING WHITE PAPER

Introduction
NCAP members have expressed an interest in testing patients for COVID-19 in their communities. NCAP strongly recommends that members carefully conduct their own research before moving forward. The tests, rules, guidance, and regulations are changing rapidly, and there will need to be significant resources reviewed and created in order to conduct testing properly.

For the convenience of members who may be interested in providing testing in North Carolina, we have developed this white paper to assist you and your legal counsel in deciding whether to proceed. If you decide to move forward, this resource will provide information on how to possibly proceed, with the realization that there is not one right way to do so. This document does not constitute legal advice nor is it meant to be all encompassing, but rather it is to serve as a resource to assist member pharmacists and pharmacies with the testing process.

On April 8th, the U.S. Department of Health and Human Services (HHS) issued guidance authorizing pharmacists to order and administer FDA authorized COVID-19 tests. This guidance was issued pursuant to the Declaration of Emergency under the Public Readiness and Emergency Preparedness Act (PREP Act).


Does this declaration allow pharmacists to test for COVID-19 in North Carolina?

NCAP believes it does for the period of emergency. While North Carolina already allows CLIA-waived tests to be administered by pharmacists with no additional regulations, the PREP Act contains express preemption language to allow for an expanded role for pharmacists.

The PREP Act expressly preempts state law with regard to pharmacist testing during the period of this emergency:

During the effective period of a declaration under subsection (b), or at any time with respect to conduct undertaken in accordance with such declaration, no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that-

(A) is different from, or is in conflict with, any requirement applicable under this section; and

(B) relates to the design, development, clinical testing or investigation, formulation, manufacture, distribution, sale, donation, purchase, marketing, promotion, packaging, labeling, licensing, use, any other aspect of safety or efficacy, or the prescribing, dispensing, or administration by qualified persons of the covered countermeasure, or to any matter included in a requirement applicable to the covered countermeasure under this section or any other provision of this chapter, or under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], 42 U.S.C. § 247d-6d(b)(8)

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What tests can be ordered and administered by pharmacists?

Based upon the guidance released on April 8th by HHS, licensed pharmacists are permitted to order and administer tests that the FDA has authorized. These tests are authorized by the FDA via Emergency Use Authorizations (EUA) which are posted on its website: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

For the tests that are authorized, it is important to understand the scope of the EUAs and the setting in which testing is appropriate.

There are currently four viral tests with EUAs which can be performed at the point of care by a provider as opposed to in a laboratory certified to conduct moderate or high complexity tests. Those tests are:

1. Abbott Diagnostics Scarborough, Inc.’s ID NOW COVID-19
2. Mesa Biotech Inc.’s Accula SARS-Cov-2 Test
3. Cepheid’s Xpert Xpress SARS-CoV-2 test
4. Quidel Corporation’s Sofia 2 SARS Antigen FIA

We anticipate more COVID-19 point of care tests will be granted EUAs. For these tests, pharmacists will need to have a CLIA waiver.

How do I get a CLIA waiver?


3: Send application to:

NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES Division of Health Service Regulation/CLIA Certification
2713 Mail Service Center
Raleigh, NC 27699-2713
(919) 855-4620
FAX: (919) 733-0176

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Where can these tests be obtained?

If a pharmacy cannot obtain these tests and necessary diagnostic equipment from their wholesalers, pharmacists are encouraged to contact the manufacturers directly.

Is there potential liability in connection with ordering and administering COVID-19 tests?

The PREP Act provides immunity from liability (except for willful misconduct) for claims of loss caused, arising out of, relating to, or resulting from administration or use of countermeasures to diseases, which here would be administration or use of FDA authorized COVID-19 tests.

Nonetheless, pharmacies are advised to speak with their counsel as there may be additional liabilities, such as not complying with applicable guidelines for PPE or specimen handling. Pharmacists should also speak with insurance professionals to ensure appropriate coverage is obtained prior to implementing testing.

Can a pharmacy serve as a specimen collection station for a laboratory test which is not a point of care test?

While specimen collection is typically performed by approved clinical laboratories, during the period of emergency, based on NCBOP guidance NCAP believes that pharmacies can act as specimen collection stations under federal law. For these tests, NCAP recommends that you seek legal counsel and work closely with the laboratory/test manufacturer to ensure compliance with the law. Again, any such tests will need to have received an EUA by the FDA.

Can a pharmacy order and administer a COVID-19 antibody test?

HHS has approved pharmacists to perform FDA authorized antibody tests. Based on this guidance, there are currently no point of care antibody tests that pharmacists can administer. A number of moderate and high complexity antibody tests have received EUAs from the FDA, however these can only be conducted by approved clinical laboratories.

Several companies are currently marketing antibody tests without EUAs to pharmacists. While the FDA has a process in place and requirements for certain tests to proceed without an EUA, this does not change the fact that pharmacists are not approved by HHS to order and administer tests without an EUA or standard FDA approval.

Should I report test results to the North Carolina Department of Health and Human Services (NCDHHS)?

All positive test results must be reported via phone or fax to local health departments who will then communicate the collected data with NCDHHS via the North Carolina Electronic Disease Surveillance System.
If a pharmacy is considering serving as a specimen collection station, they are advised to discuss reporting with the laboratory conducting the testing as they will likely handle any necessary public reporting. The North Carolina Board of Pharmacy (NCBOP) requires COVID-19 test results to be reported to the patient and the patient’s health care provider.

**Does HIPAA allow for sharing test results with NCDHHS?**

Yes, the HIPAA Privacy Rule allows sharing of otherwise protected health information without individual authorization to public health authorities such as NCDHHS. Please see the link below for additional information regarding HIPAA during this nationwide public health emergency.


**What about payment for testing?**

This issue is complicated and one in which NCAP is not in a position to provide specific answers. Two of Congress’ relief packages discuss coverage for COVID-19 tests by private and public health plans with no cost sharing to insureds. However, there are more questions than answers with regard to implementation. Additionally, most pharmacies do not have contracts with health insurers that cover testing.

Pharmacies seeking reimbursement are encouraged to reach out to health insurers directly. Pharmacies without applicable contracts with insurers may also consider charging a cash price to patients and providing them with a receipt to seek reimbursement from their insurer. However, it would be important to make no guarantees to patients regarding reimbursement by insurers.

On May 8th, 2020, CMS issued guidance which permits Medicare pharmacies to temporarily register as independent clinical diagnostic laboratories for the duration of this COVID-19 public health emergency. This allows pharmacies to bill Medicare for COVID-19 testing. Pharmacies can enroll by calling the North Carolina MAC hotline, which is Palmetto GBA, LLC. Among other information, a CLIA certificate number is required. For most COVID-19 viral tests, Medicare is reimbursing around $51.53 per test. Based on the policy for assignment of payment, the payment issued by Medicare must be accepted in full for diagnostic tests. More information on this process can be found here:


The Health Resources & Services Administration may also provide reimbursement opportunities for uninsured individuals. Please visit the following link for more information and to register:

https://www.hrsa.gov/coviduninsuredclaim

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What about PPE (Personal Protective Equipment) and other health considerations?

Pharmacies should select appropriate PPE and provide it to personnel in accordance with OSHA PPE Standards which can be found at the following link:

https://www.osha.gov/SLTC/covid-19/standards.html

Depending on types of tests and specimens, there may be additional requirements. Below are relevant federal regulations for consideration.

Personal Protective Equipment (29 CFR 1910.132);

Respiratory Protection (29 CFR 1910.134);

OSHA’s Bloodborne Pathogens (29 CFR 1910.1030); see also bloodborne pathogens model https://www.osha.gov/Publications/osha3186.html

Pharmacies should work with their regular wholesalers and supply chain to obtain necessary PPE. If your pharmacy is in critical need of PPE and has exhausted all other options for ordering, you may request PPE through the Health Care Partners PPE request form: https://covid19.ncdhhs.gov/information/health-care/requesting-ppe

Getting Started

Before ordering materials or starting to test, you should develop a business plan. Your business plan should provide a clear answer to the question, “Why do I want to be involved in COVID-19 testing?” Operational issues should be addressed and answered as well. Keep in mind that your plan will most likely change after you get started.

Business Plan

1. Is COVID-19 testing planned as a profit center? What are the additional expenses of testing and revenues needed to cover those expenses while also generating a profit?

2. Is testing something you want to provide to your patients as a community service for free? At cost? Remember, many testing locations are offering free tests.

Operational Concerns/Issues (the questions and considerations below are not all inclusive, but rather provided as a minimum to aid in your decision to test for COVID-19)

1. Where will the testing take place?

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- Many pharmacies do not have areas inside their store that provide separation between staff, customers, and patients waiting for testing. Unless there is clear separation, pharmacists may want to consider testing outside of the pharmacy. For example, a drive through area in the parking lot could be used or another area that does not require the patient to leave their car.
- Will there be adequate space in your parking area?
- Will testing have to be done in an offsite area?
- Have you made provisions, such as tents, to protect staff and patients from the weather?
- How will you organize and protect the testing samples?
- Who will direct the traffic flow?

2. What about conducting testing inside a large open area such as a gym or church meeting hall?
- What arrangements will need to be made to maintain social distancing?
- Should you schedule appointments in order to avoid large gatherings?
- Are there insurance, liability, or compliance concerns?

3. Who will be conducting the testing? Is there adequate staff?
- The HHS Guidance is clear in stating that pharmacists are allowed to order and perform FDA authorized tests. NCAP interprets this to mean that ONLY licensed pharmacists may perform the test.

4. Do you have an adequate supply of PPE on hand to conduct testing?
- Is staff trained in the proper doffing and donning of PPE?

5. How will you track tests and report test results, including notifying the patient and sharing the information with the state?
- See “Should I report test results to the North Carolina Department of Health and Human Services (NCDHHS)?” section.

6. Where will you obtain the tests?
- Are tests and testing equipment available through your wholesaler?
- Can you obtain tests from the manufacturer or an authorized dealer?

7. Once you have built your business and operational plan, how do you get started?
- If you are planning on conducting point of care testing, you will need to plan for a pharmacist to assist with test administrations, as well as interpretation, discussion with the patient, and possibly reporting.
- Some pharmacies have reached out to laboratories in their areas and are working in conjunction with them. If you decide to collaborate with an existing laboratory for non-CLIA waived tests, you will likely only be performing specimen collection and not interpreting test results or reporting test results.

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