Pharmacy Practice:
How Pharmacies May Become COVID-19 Testing Centers

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According to Johns Hopkins University & Medicine, there were over 400,000 confirmed cases of the novel SARS-CoV-2 (COVID-19) virus in the United States as of April 8, 2020. One of the urgent challenges facing policy makers in stemming this public health crisis is figuring out how to ramp up diagnostic testing on a mass scale. Pharmacies and pharmacists are likely to become instrumental in the coming weeks and months in testing for COVID-19. Here, we address some of the fundamentals of how pharmacies and pharmacists may become engaged to help test patients for COVID-19.

Specimen Collection and Point-of-Care Testing

To ensure the accuracy, quality, and reliability of laboratory testing results, the Clinical Laboratory Improvement Amendments of 1988 (CLIA) requires laboratories to meet standardized certification parameters in order to perform tests on human specimens. However, if a laboratory test could be performed with "a minimal level of complexity and low risk of erroneous results," an exception could be granted to perform this testing in a non-laboratory setting (e.g., pharmacy, clinic, or other non-laboratory setting). Those excepted tests are known as CLIA-waived tests. Before initiating point-of-care testing (POCT), pharmacies must obtain a CLIA Certificate of Waiver or Certificate of Compliance through their state office of the Centers for Medicare and Medicaid Services (CMS). An alternative to POCT occurs where a pharmacy collects a specimen from a patient and sends that specimen to a reference lab for testing. The specifics of each of these methods is explored briefly below.

A. Specimen Gathering

For pharmacies that engage in specimen-gathering activities for testing to occur at a CLIA-certified laboratory, there is generally no requirement that the pharmacy hold a CLIA Certificate of Waiver. This is because the tests are to be performed by the laboratory, not the pharmacy. This also allows for self-collection of specimens by patients that some pharmacies are utilizing as part of their specimen gathering efforts.

The FDA recommends that pharmacies participating in public health testing for COVID-19 communicate with local and state public health staff to determine which persons meet the criteria for testing. State and local health departments will inform pharmacies about procedures to collect, store, and ship specimens appropriately, including after hours or on weekends/holidays.

Pharmacies should also consult with the laboratories that will be conducting the specimen testing to determine additional requirements for proper specimen gathering. Many state health departments have specific requirements regarding (i) pre-approval for submissions to certain laboratories; (ii) testing criteria; (iii) specimen types; (iv) specimen collection and handling; (v) specimen shipping; and (vi) results reporting for public health laboratories. For example, the Texas

Department of Health and Human Services has promulgated rules for each of the above criteria and has very specific requirements which must be followed for the specimen to be valid for testing. These include strict storage requirements and pre-authorization to collect the specimen. Private CLIA-certified laboratories may have similar requirements that would need to be reviewed with that particular laboratory prior to specimen gathering.

B. Point-of-Care Testing

For pharmacies that hold a CLIA Certificate of Waiver or are planning on obtaining certification, POCT is an option. POCT are tests that can be conducted entirely within clinics, pharmacies, or even the parking lot of a mobile drive-through testing site. These tests are helpful for letting medical professionals know right away if a patient has COVID-19. Many companies are rolling out POCT and the FDA is authorizing their immediate use under an Emergency Use Authorization (EUA). All FDA tests approved under an EUA for COVID-19 use at the point-of-care are CLIA-waived. Accordingly, for the duration of the emergency declaration, such tests can be performed in a patient care setting that is qualified to have the test performed there as a result of operating under a CLIA Certificate of Waiver or Certificate of Compliance.

Current POCT technology for COVID-19 requires a proprietary piece of equipment usually around the size of a toaster, and a set of one-time-use cartridges that contain all the chemicals needed for the procedure. The pharmacy obtains a sample from the patient (this typically requires a nasopharyngeal throat and nose swab for COVID-19 patients), which is inserted into the cartridge. The cartridge goes into the testing device, which heats and cools it to facilitate the proper chemical reactions. Results typically come back in less than an hour—one point-of-care-test recently approved under an EUA by the FDA was developed by Abbott Laboratories and claims to produce results in as little as five minutes.

C. State Laws

One potential barrier to POCT is the variability and limitations of state laws and regulations. Only a handful of states have regulations in their state pharmacy practice acts regulating POCT (e.g., California, Colorado, Georgia, New Jersey, North Dakota, Pennsylvania, and Washington). However, almost all states have laws and regulations that address collaborative drug therapy management (CDTM) that often address POCT. Pharmacies considering POCT should consult with their State Board of Pharmacy to determine the state laws and regulations pertaining to POCT. Pharmacies may also consider seeking waivers from their State Board of Pharmacy and Board of Health to allow expanded in-pharmacy sample collection and testing during this COVID-19 outbreak.

Pharmacy advocacy groups believe that permitting pharmacists to administer COVID-19 tests can free up resources and better attack this crisis by freeing up other medical resources. On March 13, 2020, the American Pharmacists Association (APhA) sent a letter to Vice President Mike Pence advocating for the President's Coronavirus Task Force (Task Force) to encourage states to permit pharmacists to administer COVID-19 tests. One recommendation includes encouraging states to let pharmacists administer COVID-19 tests as a rapid diagnostic test. This can be accomplished through Collaborative Practice Agreements and current state laws.

D. Summary

For many pharmacies, collaboration with CLIA laboratories and specimen gathering are the easiest and quickest path in assisting in COVID-19 testing efforts. Unlike POCT, specimen gathering usually does not require pharmacies to obtain a CLIA Certificate of Waiver beforehand. Furthermore, traditional reaction testing machines at laboratories typically have 96-well plates and can test and handle 96 samples in a single batch, unlike a POCT machine which can only test one sample at a time. Thus, while POCT may be able to provide quicker answers for individual patients, they cannot handle a large number of tests.

Personal Protective Equipment

Pharmacy staff conducting COVID-19 specimen gathering and/or POCT should comply with FDA and CDC recommendations for personal protective equipment (PPE). These procedures and other close-contact patient care procedures will likely elicit coughs or sneezes from which pharmacy personnel will need to be protected. The CDC recommends that health care personnel who are performing nasopharyngeal swabs on a known or suspected COVID-19 patient wear an N95 or higher-level mask (or a facemask if an N95 or equivalent mask is not readily available), eye protection, gloves, and a gown.

The CDC allows the use of KN95 masks, when N95 masks are not available, as a "suitable alternative" when N95 mask supplies are in short supply. The CDC has also permitted multiple other types of foreign-sourced masks, that are the equivalent of N95 masks, to provide protection during the COVID-19 response when local supplies are unavailable. These now include KN95 masks sourced from China.

When supplies of N95 masks are low, the CDC allows the re-use of N95 masks by health care personnel for multiple encounters with different patients; however that N95 mask needs to be removed after each encounter. N95 masks and other disposable respirators should not be shared by multiple health care personnel.

At this time, the CDC is also allowing the use of expired N95 masks for care of patients with COVID-19.

Finally, if no face masks are available, some options recommended by the CDC include:

- Excluding health care personnel, at higher risk for severe illness from COVID-19, from contact with known or suspected COVID-19 patients (e.g., older persons, those with chronic medical conditions, and those who are or may be pregnant);
- Using a face shield that covers the entire front (extends to the chin or below) and side of the face; and
- The use of homemade masks (e.g., bandana, scarf) as a last resort.

What We Know and What We Expect

Many states currently allow pharmacies to either (i) collect specimens from patients for testing at a reference lab or (ii) perform POCT tests onsite pursuant to a CLIA Certificate of Waiver. In some states, performance of either of the above will require Collaborative Practice Agreements, standing orders or other specific legal requirements. We expect every state to loosen controls on the regulations surrounding COVID-19 tests as our country transitions from its emergent response to a global pandemic to a normalization of life and eradication of COVID-19. This effort to return to "normal life" will necessitate a massive testing of the American population and we have every reason to believe that pharmacies will be asked to play a vital role in this effort. We encourage pharmacies in states that already allow testing to explore options for providing testing and for all other pharmacies to continue to monitor the rapidly changing laws and guidance pertaining to the expansion of COVID-19 testing that is already underway and will continue.

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