COVID-19 Pharmacy COVID-19 Testing

Prepared for Sykes & Co.
by
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Sykes & Co. is committed to providing important information to its pharmacy clients as they face the COVID-19 pandemic. One of the steps that Sykes & Co. has taken is to team up with the Health Care Group of Brown & Fortunato ("B&F"), a law firm that specializes in representing pharmacies. B&F has prepared this whitepaper for Sykes & Co. to share with its pharmacy clients.

Pharmacy COVID-19 Testing

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 the test can be performed with a "minimal level of complexity and low risk of erroneous results," an exception can be granted to perform the testing in a non-laboratory setting (e.g. a pharmacy or clinic). Those excepted tests are known as CLIA-waived tests. Before a pharmacy or clinic can perform point-of-care testing (POCT), that provider must obtain a CLIA Certificate of Waiver or Certificate of Compliance from its state CMS office. Alternatively, a pharmacy or clinic can collect and send specimens to a reference lab for testing without being required to have a CLIA certificate.

Specimen Gathering

For a pharmacy engaged only in specimen gathering for testing that will occur at a CLIA-certified laboratory, there is generally no requirement that the pharmacy hold a CLIA Certificate of Waiver. However, the FDA recommends that pharmacies participating in public testing for COVID-19 communicate with local and state public health staff to determine which persons meet the criteria for testing as well as the procedures for collecting, storing, and shipping specimens.

Pharmacies should also consult with the laboratories that will be conducting the testing to determine any additional requirement 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. Additionally, private CLIA-certified laboratories may have similar requirements that the pharmacy will need to review with that particular lab prior to specimen gathering.

Point-of-Care Testing ("POCT")

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 the clinic, pharmacy, or even the parking lot of a mobile drive-through testing site.

Many companies are rolling out POCT, and the FDA is authorizing their immediate use under its power to issue an Emergency Use Authorization. All FDA approved tests under an EUA for COVID-19 use at the point-of-care are CLIA-waived.

Current POCT technology for COVID-19 requires a proprietary piece of equipment set with one-time-use cartridges with all the necessary testing chemicals. Results typically come back in less than one hour.

State Laws

In addition to federal statutory and regulatory compliance, pharmacies must also confirm that POCT is permitted under their specific state's laws and regulations. Some states, such as California, Colorado, Georgia, New Jersey, North Dakota, Pennsylvania, and Washington, have regulations in their pharmacy practice acts regulating POCT. Pharmacies considering POCT should consult with their state Board of Pharmacy to identify the specific regulations and requirements in their state. Pharmacies may also consider seeking waivers from their state Board of Pharmacy and Board of Health to allow for expanded in-pharmacy collection and testing during this COVID-19 outbreak.

Personal Protective Equipment ("PPE")

Pharmacy staff conducting COVID-19 specimen gathering and/or POCT should comply with FDA and CDC recommendations regarding the use of PPE. 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.

If N95 masks are not available, the CDC has approved the use of KN95 as a "suitable alternative." Also, the CDC has permitted multiple other types of foreign-sourced masks that are the equivalent of N95 masks when local supplies are unavailable.

When supplies of N95 are scarce, the CDC allows the re-use of N95 masks by health care personnel for multiple encounters with different patients. However, the N95 masks need to be removed after each encounter. N95 masks and other disposable similar products should not be shared between multiple health care personnel. Also, at this time, the CDC is 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 a higher risk for severe illness from COVID-19 (e.g., older persons, those with chronic medical conditions, and those who are or who may be pregnant) from contact with known or suspected COVID-19 patients;

- 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.

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