Pharmacy Models for COVID-19 Testing

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As the response to the COVID-19 pandemic continues to unfold, pharmacists and pharmacies across the country are mobilizing to support their communities through COVID-19 testing. Pharmacy testing models have emerged due to the ongoing effort to expand access to testing. This guide will provide an overview of two common models and the payment mechanisms associated at this time. This resource outlines a stepwise approach to COVID-19 testing and payment.

Pharmacy Testing Model #1: Specimen Collection in Partnership with a Laboratory

In this model, the pharmacy partners with a CLIA high or moderate complexity laboratory.

- Review Testing Considerations and Requirements
- Identify a Laboratory Partner
- Obtain Testing Supplies and Personal Protective Equipment (PPE)
- Patient Assessment
- Specimen Collection
- Implement Communication Plan
- Payment for Services
- Documentation

Pharmacy Testing Model #2: Point-of-Care Testing

In this model, the pharmacist conducts the COVID-19 test at point of care using a test authorized by the FDA under an EUA for patient care settings.

- Review Testing Considerations and Requirements
- Obtain a CLIA Certificate of Waiver
- Enroll as an Independent Clinical Laboratory
- Pharmacy Obtains Testing Device, Supplies, and Personal Protective Equipment
- Patient Assessment
- Specimen Collection
- Conduct Point-of-Care Test
- Implement Communication Plan
- Payment for Services
- Documentation

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Pharmacy Testing Model #1: Specimen Collection in Partnership with a Laboratory

Review Testing Considerations and Requirements: Be familiar with Centers for Disease Control and Prevention (CDC) guidance related to COVID-19 testing and the specific requirements in your area. Understand the different types of COVID-19 tests and how FDA defines and approves COVID-19 tests.

Identify a Laboratory Partner: Reference local and state health departments to coordinate testing with an authorized laboratory.

Obtain Testing Supplies and Personal Protective Equipment (PPE): The pharmacist will either obtain testing supplies directly from the laboratory or purchase the testing supplies separately. Consider necessary PPE supplies prior to implementing testing.

Patient Assessment: The patient is assessed by the pharmacist or is assessed and referred to the pharmacy by another health care provider.

Specimen Collection: The pharmacist either collects the specimen or supervises patient self-collection. Workflow procedures used for specimen collection can vary depending on whether specimen collection takes place indoors or outdoors. Once collected, the specimen is sent to the partnering laboratory.

Implement Communication Plan: Establish and implement a communication plan between the pharmacy and the laboratory to ensure the patient, state health department, and necessary providers receive the results of the test.

Payment for Services: Payment for COVID-19 testing depends on whether the patient receiving the test is insured by Medicare, Medicaid, or private insurance, or is uninsured, and whether the payer recognizes the pharmacy or pharmacist for payment.

Documentation: Document the patient encounter and required elements from the communication plan.

Pharmacy Testing Model #1: Specimen Collection in Partnership with a Laboratory

In this model, the pharmacy partners with a Clinical Laboratory Improvement Amendment (CLIA) high or moderate complexity laboratory. The pharmacist collects samples for a COVID-19 test authorized under a Food and Drug Administration (FDA) Emergency Use Authorization (EUA) and sends the specimen to the laboratory for processing. It is not necessary for the pharmacy to obtain a CLIA Certificate of Waiver.

How do I identify a laboratory to partner with?

In this model, the primary responsibility of the pharmacy/pharmacist is to collect the specimen from the patient for processing at a laboratory. To identify a potential laboratory partner, pharmacists can begin by referencing information available from their local and state health departments or board of pharmacy. The pharmacist can either work with their local and state health departments to coordinate testing through public health laboratories or work with commercial or clinical laboratories using COVID-19 tests authorized by the FDA EUA.

How do I determine which tests are authorized by the FDA?

The FDA's list of tests with EUAs provides links to each test's Letter of Authorization, which contains the section "Authorized Laboratories and Other Authorized Testing Locations." This list can be referenced when partnering with a laboratory.

Are states allowing pharmacists to collect specimens for COVID-19 tests that are considered moderate or high complexity testing?

Yes. Pharmacists can partner with a CLIA-certified high or moderate complexity laboratory to collect respiratory specimens for FDA EUA COVID-19 tests.

What should I know about specimen collection?

Depending on the test, either the pharmacist will collect the respiratory specimen, or the patient will "self-collect." Review CDC's Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19. The PPE requirements and workflow considerations will differ depending on who collects the specimen and whether the collection is done outside or inside the pharmacy.

BACK TO MODEL #1. »

Can a pharmacist receive payment for specimen collection for Medicare patients?

Currently, pharmacists cannot receive direct payment from Medicare for specimen collection. If a pharmacist is employed by a hospital, or contracted with a physician, or contracted with a high throughput laboratory, payment for the pharmacist specimen collection service occurs according to the following parameters:
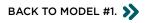
- **Specimen Collection in a Hospital Outpatient Department:** HCPCS Code C9803 can be used when clinical staff (pharmacists) conduct assessment and specimen collection leading to an order or administration of a COVID-19 test. In this example, the hospital bills for the pharmacist collecting the specimen.

- **Specimen Collection under Contract with a Physician:** Pharmacists' basic clinical services may be covered through a contract with a Medicare-enrolled provider in accordance with scope of practice and state law. These services may include symptom and exposure assessment and specimen collection. Since pharmacists are not considered providers who can bill for services under Medicare, the pharmacist must be paid for basic clinical services under an "incident-to physician services arrangement." This is an agreed-upon financial relationship in which the physician or other qualified nonphysician practitioner (NPP) bills Medicare for the services provided by the pharmacist and then reimburses the pharmacist under the terms of the financial relationship. CMS has established that evaluation and management services CPT Code 99211 be used to bill for testing-related services provided by clinical staff (pharmacists) to new and established patients during the public health emergency.

  Note: *Normally, the pharmacist is required to be directly supervised by the physician or NPP, which requires the pharmacist to practice within the physician or NPP office. During the public health emergency, this requirement has been relaxed. Rather than direct supervision, the physician or NPP must at least be immediately available using real-time audio and visual technology.*

- **Specimen Collection under Contract with a High Throughput Laboratory:** CMS has indicated that pharmacists can contract with Medicare high throughput laboratories to provide specimen collection services. Pharmacists can be reimbursed based on the terms of the contract with the laboratory.

How can pharmacists receive payment for specimen collection from other payers like Medicaid, private sector plans, and employers?

Pharmacists can receive payment for providing specimen collection services, including assessment and screening. Pharmacists should consult with the specific payer to determine whether they are included in the payer's provider network for COVID-19 services, and if so, what services are covered and what the parameters are for coverage.

Pharmacy Testing Model #2: Point-of-Care Testing

Review Testing Considerations and Requirements: Be familiar with CDC guidance related to COVID-19 testing and the specific requirements in your area.

Obtain a CLIA Certificate of Waiver: Obtain a CLIA Certificate of Waiver by filling out an application and submitting it to the appropriate state authority.

Enroll as an Independent Clinical Laboratory: Enroll the pharmacy as an independent clinical laboratory to collect payment for testing under Medicare by submitting a CMS-855B enrollment application to the Medicare Administrative Contractor (MAC) serving your geographic area.

Pharmacy Obtains Testing Device, Supplies, and Personal Protective Equipment: Refer to the FDA's list of tests with an EUA to identify tests that can be conducted in patient care settings (Letter "W" under authorized settings). Conduct an evaluation of the most appropriate testing device and purchase for the pharmacy. Consider necessary PPE supplies prior to implementing testing.

Patient Assessment: The patient is assessed by the pharmacist or is assessed and referred to the pharmacy by another health care provider.

Specimen Collection: The pharmacist either collects the specimen or supervises patient self-collection.

Conduct Point-of-Care Test: The specimen is processed at the point of care to obtain results.

Implement Communication Plan: In this model, the pharmacist must establish and implement a communication plan that includes reporting requirements to ensure the patient, state health department, and necessary providers receive the results of the test. Pharmacists should be aware that reporting requirements in some states may require reporting of both positive and negative results. Reporting may also have to be completed manually by the pharmacist. Pharmacists should also consider follow-up communication procedures and referral to primary care.

Payment for Services: Payment for COVID-19 testing depends on whether the patient receiving the test is insured by Medicare, Medicaid, or private insurance, or is uninsured, and whether the payer recognizes the pharmacy or pharmacist for payment.

Documentation: Document the patient encounter and required elements from the communication plan.

Pharmacy Testing Model #2: Point-of-Care Testing

In this model, the pharmacist conducts the COVID-19 test at point of care using a test authorized by the FDA under an EUA for patient care settings. Pharmacists should obtain a CLIA Certificate of Waiver or make sure their current waiver is up to date before providing point-of-care testing at the pharmacy. In this model, the pharmacist assesses the patient, the pharmacist or patient collects a specimen, and then the pharmacist uses the testing machine to run the test.

How do I obtain a CLIA Certificate of Waiver?

To offer testing for COVID-19 at the point of care, the pharmacist must obtain a CLIA Certificate of Waiver for the pharmacy by filling out an application and submitting it to the appropriate state authority. You will need to identify the COVID-19 test being used in the pharmacy on the application. This process can take some time, so it is an important step to take now if your pharmacy wishes to provide point-of-care testing as these tests become more widely available. If your pharmacy already has a CLIA Certificate of Waiver, you may still need to update your application to indicate the COVID-19 test you will be using in your pharmacy.

Note: *In some states, there may be limitations that make it difficult for licensed pharmacists to obtain a CLIA Certificate of Waiver. HHS guidance (see above) preempts any state or local requirement that directly or indirectly prohibits a pharmacist from ordering or administering COVID-19 tests. If barriers in your state need to be addressed, reach out to your state pharmacy association.*

How do I enroll my pharmacy as an Independent Clinical Laboratory under Medicare?

To offer testing for COVID-19 at the point of care, pharmacies with a CLIA Certificate of Waiver should enroll as an independent clinical laboratory to collect payment for testing. A CMS-855B enrollment application must be completed and sent to the Medicare Administrative Contractor (MAC) serving your geographic area. During the period of the public health emergency, CMS has waived Medicare enrollment fees. Once enrolled, the pharmacy bills for COVID-19 tests using the appropriate diagnosis and billing codes and is paid based on Medicare Administrative Contractor (MAC) COVID-19 Test Pricing.

Note: *Pharmacies will be assigned a Medicare provider number called a PTAN (Provider Transaction Access Number).*

How do I determine which tests are authorized at point of care?

The FDA's list of tests with EUAs provides links to each test's Letter of Authorization and describes the authorized setting. FDA must authorize the test for "patient care settings" or otherwise authorize the test for use at the point of care for pharmacists to be able to administer the test at a pharmacy with a CLIA Certificate of Waiver. These tests will list the letter "W" in this column.

What payment opportunities are there for pharmacists' COVID-19 testing under Medicare?

CMS has described payment opportunities for conducting a COVID-19 test and for some testing-related services. Medicare will pay pharmacies enrolled in Medicare as an independent clinical laboratory for COVID-19 tests performed by pharmacists. CMS has also described several opportunities for pharmacists to contract with a Medicare provider for COVID-19 testing-related services and be paid by that provider. With this payment option, pharmacists are not directly paid by CMS.

Note: *It is important to know that CMS states there is no beneficiary cost sharing for COVID-19 testing and services during the public health emergency.*

How would a pharmacy receive payment by Medicare for conducting COVID-19 tests as part of a Medicare-enrolled laboratory?
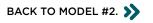
The pharmacy will need a CLIA Certificate of Waiver and will need to enroll in Medicare as an Independent Clinical Laboratory (see above). Using the PTAN assigned to the pharmacy for purposes of COVID-19 testing, the pharmacy can bill their local Medicare Administrative Contractor (MAC) for COVID-19 tests by referencing this list of billing codes. Pharmacies will likely need to contract with an intermediary company that can convert NCPDP claims to medical (X12-837) claims for submission to the MAC because Medicare payment for COVID-19 tests occurs through the medical benefit.

Note: *Pharmacies can also conduct and receive payment for influenza and/or RSV if the tests are performed concurrently with a COVID-19 test and allowed by state law. See the list of billing codes to identify the code that best reflects the tests conducted.*

How would a pharmacist receive payment by Medicare for COVID-19 testing-related services?

Basic Clinical Services: Pharmacists are not paid directly under Medicare, but pharmacists' "basic clinical services" can be covered via contract with a Medicare-enrolled provider in accordance with scope of practice and state law. These services may include symptom and exposure assessment and specimen collection. Since pharmacists are not considered providers who can bill for services under Medicare, the pharmacist is paid for basic clinical services under an "incident-to physician" services arrangement. This is an agreed-upon financial relationship where the physician or other qualified nonphysician practitioner (NPP) bills Medicare for the services provided by the pharmacist and then reimburses the pharmacist under the terms of the financial relationship. CMS has established that evaluation and management services CPT Code 99211 be used to bill for testing-related services provided by clinical staff (pharmacists) to new and established patients during the public health emergency.

Note: *Normally, the pharmacist is required to be directly supervised by the physician or NPP, which requires the pharmacist to practice within the physician or NPP office. During the public health emergency, this requirement has been relaxed. Rather than direct supervision, the physician or NPP must at least be immediately available using real-time audio and visual technology.*

How would a pharmacist receive payment by Medicare for COVID-19 testing-related services? *(continued)*

Specimen Collection: In some cases, payment for pharmacists engaged in collecting respiratory samples may occur in the following settings:
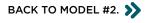
- **Specimen Collection in a Hospital Outpatient Department:** HCPCS Code C9803 can be used when clinical staff conduct assessment and specimen collection leading to an order or administration of a COVID-19 test. In this example, the hospital bills for the pharmacist collecting the specimen.

- **Specimen Collection by a Laboratory:** HCPCS Codes G2023 and G2024 can be used by Medicare laboratories (pharmacies) for specimen collection in a patient's home or for an individual in a skilled nursing facility (SNF)/by a home health agency (HHA), respectively. Note that these codes cannot be used for specimen collection in a pharmacy, even if the pharmacy is a CLIA-waived laboratory.

How can pharmacists receive payment from other payers like Medicaid, private sector plans, and employers?

Pharmacists can provide a comprehensive set of COVID-19 testing-related services, including assessment and screening, ordering, specimen collection, interpreting results, notifying and educating the patient, and reporting the test results to the proper public health entities. Pharmacists should consult with the specific payer to determine whether pharmacists are included in the payer's provider network for COVID-19 services, and if so, what services are covered and what the parameters are for coverage.

NCPDP and intermediary companies for medical billing have guidance available and can be sources of information related to billing for COVID-19 testing and testing-related services.

Testing Considerations and Requirements

What is my authority to order and administer COVID-19 tests?

On April 8, 2020, the U.S. Department of Health and Human Services (HHS) issued guidance that authorizes pharmacists to order and administer certain tests authorized by the Food and Drug Administration (FDA) for COVID-19. HHS recently released an advisory opinion that confirms the Administration's intent and confidence in pharmacists to order and administer COVID-19 tests. HHS is clear that this guidance preempts any state or local requirement that directly or indirectly prohibits a pharmacist from ordering or administering COVID-19 tests; however, pharmacists will still need to obtain a CLIA Certificate of Waiver to conduct waived tests.

How can I determine state requirements for COVID-19 testing?

Pharmacists interested in providing COVID-19 testing should refer to their board of pharmacy to identify state-based considerations or restrictions to testing provided by pharmacists and can reference the National Alliance of State Pharmacy Associations (NASPA) COVID-19 Testing webpage to view information about state actions related to testing. Pharmacists may reach out directly to the state survey agency responsible for overseeing laboratories and should be familiar with information available from their local and state health departments to learn about general testing requirements in their area.

What is the difference between partnering with a laboratory versus conducting a test at point of care?

When partnering with a laboratory, the pharmacist performs specimen collection, which involves collecting respiratory samples for FDA EUA COVID-19 tests. These samples are then sent to and processed at a CLIA high or moderate complexity laboratory. In this model, it is not necessary for the pharmacy to obtain a CLIA Certificate of Waiver. The test results are reported to appropriate officials and to the patient, according to the communication plan established between the laboratory and the pharmacy.

To conduct a test at point of care, the pharmacist would use a COVID-19 test authorized by the FDA for patient care settings. Pharmacies are considered by FDA to be patient care settings. Pharmacists should obtain a CLIA Certificate of Waiver or make sure their current waiver is up to date before providing testing at the pharmacy. In this model, the pharmacist assesses the patient, the pharmacist or patient collects a specimen, and then the pharmacist uses the testing machine to run the test and interpret the results. The pharmacist is then responsible for reporting the results of the test to the state health department or other entity and the primary care provider as appropriate. Pharmacists should follow state health department guidance on reporting the test results to the patient and educating the patient.

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What additional considerations need to be made before providing COVID-19 testing?

Personal Protective Equipment: Consider your supplies of personal protective equipment (PPE) and establish a plan for maintaining an adequate supply of PPE while providing testing at the pharmacy. Patients presenting to the pharmacy for a COVID-19 diagnostic test are considered a "suspected case," or person under investigation under investigation (PUI), so it is important to refer to CDC's Interim Infection Prevention and Control Recommendation for Patients with Suspected or Confirmed COVID-19 in Healthcare Settings. When collecting specimens and/or within 6 feet of a PUI, recommended PPE includes an N95 or higher-level respirator (or surgical facemask if respirator is not available), eye protection, gloves, and a gown. For providers handling specimens, but not directly involved in collecting the specimen (e.g., self-collection) and not working within 6 feet of the PUI, a facemask and gloves are recommended. Pharmacists should also review OSHA's PPE standards (29 CFR 1910 Subpart I) and OSHA's COVID-19 Guidance for Retail Pharmacies.

If obtaining PPE will be a challenge for your pharmacy, consider tests that are designed for patient self-collection, which generally have less stringent PPE requirements. The pharmacist facilitates the self-collection process using strategies such as maintaining 6 feet and utilizing barriers such as a car window or drive-through window. For example, a pharmacist could bring the testing supplies to a patient's car using a cart while the car window is rolled up. The pharmacist would step away and observe the self-collection from 6 feet before retrieving the sample from the patient after the window is rolled back up. The PPE requirement for this method is gloves and a facemask.

Medical Waste Disposal: Review your state environmental quality agency regulations to determine waste disposal requirements associated with COVID-19 testing in your state. At a minimum, biohazard pick up should be coordinated, as necessary. View the CDC's Frequently Asked Questions about Biosafety and COVID-19.

Pharmacy Workflow: Consider how patients will be tested at your site, develop a workflow for testing, and educate your staff about the process for your pharmacy. "Parking-lot" or "drive-thru" models are encouraged to reduce the risk of COVID-19 testing in the pharmacy. It is important to consider the need for materials such as signs, tents, and cones to help manage the flow of traffic. If testing will be conducted inside the pharmacy, identify a private space or a low-traffic area, and develop workflows that minimize exposure.

Depending on the testing volume, pharmacies may need to increase the number of pharmacists and staff to support this service. Pharmacy managers may want to designate "testing hours" and/ or require that testing appointments be made during periods of pharmacist overlap. With warmer weather approaching, pharmacy managers may want to consider testing hours during cooler times of the day if the specimen collection will take place outdoors. Proper cleaning and disinfection protocols in areas where testing is being conducted need to be implemented. Review CDC's Guidance for Pharmacies and look for COVID-19 Drive-Through Testing/Community Screening Resources from your local and state health departments.

Frequently Asked Questions About Pharmacy Models for COVID-19 Testing

How do I conduct patient assessment and screening prior to ordering a test?

Pharmacists can play an important role in assessing whether patients are at high risk of severe illness. In some cases, other providers will assess the patient and refer them to the pharmacist/pharmacy for specimen collection and testing. In cases where the patient presents to the pharmacist for assessment and screening, pharmacists should be familiar with the symptoms of COVID-19. The CDC outlines priorities for testing and guidance for Evaluating and Testing Persons for COVID-19. Pharmacists should also refer to state and local health department guidelines for priority testing.

How do I implement a communication plan?

A communication plan must be established for reporting results to the proper individuals and agencies in a timely manner. Pharmacists conducting testing at point of care will generally be responsible for all reporting, whereas pharmacies that partner with a lab will need to establish a communication plan in partnership with the lab. Pharmacists should review CDC's Interim Clinical Guidance for Management of Patients with Confirmed COVID-19.

Patient: When a pharmacist informs the patient of their COVID-19 test results, the following should be considered:

- **For Positive COVID-19 Diagnostic Test Results:** Patients should know what proactive steps to take if they are sick or caring for someone.

- **For Negative COVID-19 Diagnostic Test Results:** Patients should know preventive measures to protect themselves and others, including socially distancing as appropriate. It is important to remind patients to continue to monitor their symptoms in case the test result was a false negative.

Depending on the COVID-19 testing related services offered, the pharmacist may set up follow-up appointments with the patient at designated times. Pharmacists should counsel patients with positive results that they may receive outreach from a contact tracer.

Primary Care Provider: Pharmacists should consider the communication and documentation systems available to them when following up in a timely manner with the patient's primary care provider. If the patient does not have a primary care provider, the pharmacist should facilitate referral to a primary care provider or local health department, if indicated.

Health Department: It is important to refer to requirements from your state health department when establishing a communication plan. Some state health departments require results to be reported immediately, both positive and negative. Depending on the system, results may have to be reported manually, which may require additional staffing resources.

Pharmacists wondering How to Report COVID-19 Laboratory Data should refer to laboratory data reporting guidance from HHS and can view Frequently Asked Questions: Laboratory Data Reporting for COVID-19 Testing for more information. This guidance requires laboratories performing COVID-19 testing

under a CLIA Certificate of Waiver, including pharmacies enrolled as independent clinical laboratories, to report test results and other data while the federal public health emergency declaration is in effect.

The pathways for reporting and utilizing testing data will be guided by local requirements and pharmacy providers should refer to these requirements for next steps.

How does payment for COVID-19 testing work?

Payment for COVID-19 testing varies depending on whether the patient receiving the test is insured by Medicare, Medicaid, or private insurance, or is uninsured, and whether a payer recognizes the pharmacy or pharmacist for payment. Payment for COVID-19 testing can include:

1. Payment for conducting the test and reporting the test results to the proper public health entities and;
2. Payment for COVID-19 testing-related services, which can include the following:
    1. Specimen collection
    2. Assessment and screening
    3. Ordering
    4. Notifying the patient
    5. Notifying/referring to primary care provider as appropriate

In some practices, pharmacists also conduct follow-up visits/outreach with the patient at designated intervals after the patient has been tested. For more information related to payment under Medicare, view COVID-19 Frequently Asked Questions on Medicare Fee-for-Service Billing.

> To view payment information specific to the pharmacy testing model, view either Specimen Collection in Partnership with a Laboratory or Point-of-Care Testing.

Disclaimer: *Information related to the COVID-19 pandemic is changing rapidly. The material and information contained in this publication is believed to be current as of the date included on this document. The American Pharmacists Association assumes no responsibility for the accuracy, timeliness, errors or omission contained herein. Links to any sources do not constitute any endorsement of, validity, or warranty of the information contained on any site. The user of these materials should not under any circumstances solely rely on, or act based on this publication. Pharmacy professionals retain the responsibility for using their own professional judgment and practicing in accordance with all rules, regulations, and laws governing the pharmacy practice within their jurisdiction.*