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A Guide to Implementing Point-of-Care Testing Services in Community Pharmacy

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Disclaimer: This guide provides general guidance for implementing POCT services in a pharmacy. It is essential to consult with legal and regulatory experts in your state and seek specific advice from relevant authorities to ensure compliance with all applicable laws and regulations.

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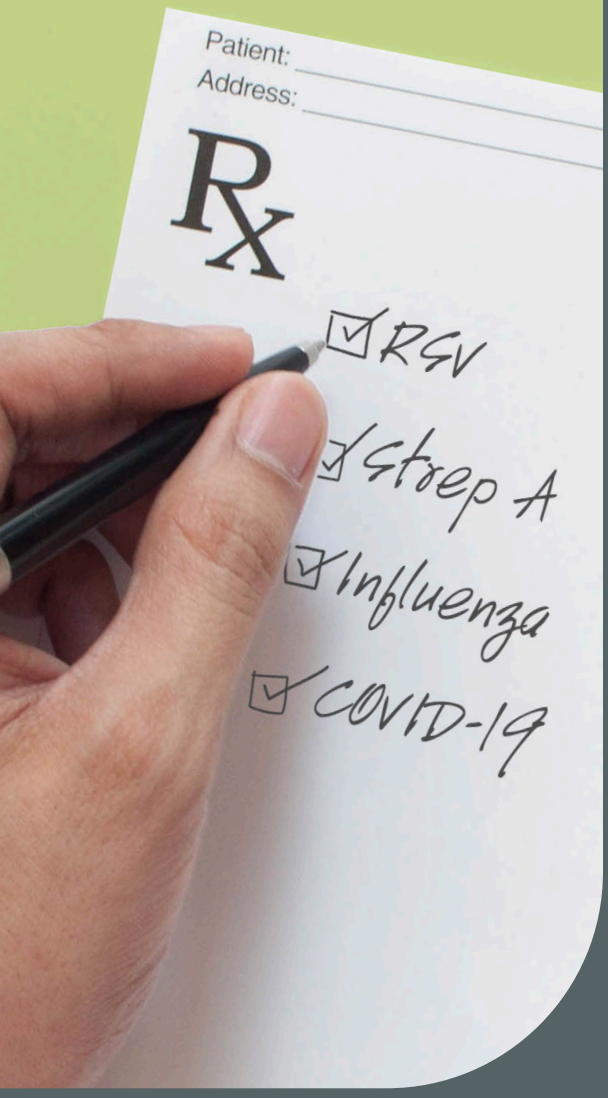
The development of this guide was supported with funding from QuidelOrtho Corporation.



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QuidelOrtho offers a range of convenient and affordable diagnostic testing solutions to help you better care for your customers, from simple and accurate OTC tests to rapid point-of-care solutions that fit seamlessly into your pharmacy workflow.

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iFOB
H. pylori

Over-the-Counter Solution — FDA EUA

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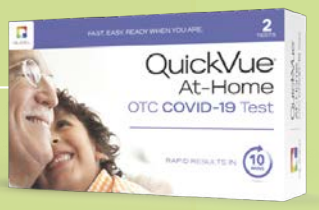

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*FDA Emergency Use Authorization (EAU) Only. This product has not been FDA cleared or approved but has been authorized by FDA under an Emergency Use Authorization. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any viruses or pathogens. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use or in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

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AD60021EN Rev. A (09/23)

INTRODUCTION

Point-of-care testing (POCT) involves screenings and tests at or near the point of care that produce rapid, reliable results aiding in the identification, monitoring, and treatment of acute infections or chronic diseases. POCT provides an excellent opportunity for community pharmacy teams to enhance patient care and expand revenue-generating services while improving health at the patient and population levels.

WHY PHARMACY?

Community pharmacies are convenient, accessible, trusted, and preferred healthcare and wellness destinations. Early identification of acute infection and chronic diseases leads to earlier diagnosis and earlier access to treatment, which can be lifesaving.

BENEFITS OF POCT FOR COMMUNITY PHARMACIES INCLUDE:

- Increased patient appreciation
- Increased staff engagement and patient impact, leading to increased job satisfaction
- Increased cash flow, including OTC sales for symptom relief
- An expanded patient base
- Opportunities to identify individuals who are candidates for other pharmacy services, like immunizations or diabetes self-management education
- Antibiotic stewardship

ORDERING TESTS: AUTHORIZATIONS AND REQUIREMENTS

Each state has specific laws or guidelines about the scope of pharmacy practice, which may include additional requirements for training and other factors related to POCT in pharmacies. Many states are silent as to POCT authorities, so best practices and continuing education can support pharmacy teams in providing POCT services to patients. Additionally, pharmacies operating as labs are also governed by state laboratory boards. These factors can significantly impact the implementation of POCT in community pharmacy settings.

BEFORE GETTING STARTED, ASK YOURSELF...

1. Based on my state law, is my pharmacy team legally allowed to:
    - Administer POC tests
    - Interpret the results of POC tests
    - Act on the results of POC tests
2. Will patients need a prescription in order for my pharmacy to provide a POC test?
3. Are Collaborative Practice Agreements (CPA) or other protocols required?
4. Do my staff and pharmacy space meet regulatory requirements for POCT?
5. What are the state requirements for reporting results?

GETTING STARTED...

1. Determine which POCT tests you want to offer
2. Determine who will be responsible for leading and overseeing POCT operations
3. Apply for a CLIA Certificate of Waiver through the Centers for Medicare & Medicaid Services (CMS)

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) APPLICATION FOR CERTIFICATION

Depending on your state rules, pharmacies need to complete an application [Form CMS-116] for a CLIA Certificate of Waiver in order to register as a CLIA-waived testing site with CMS. CLIA-waived tests include POC tests, which are simple lab tests that do not have a high risk for incorrect results. Note that some states have their own form, in addition to the CMS-116 form, that needs to be completed.

The CLIA Application requests details about the lab director and any POC tests that will be performed, including the names of specific tests that will be used. There is also a question about "Estimated Total Annual Test volume" that is often overlooked but must be completed. A list of CLIA Waived POC tests are available on the Food and Drug Administration (FDA) website.

Analyte/Test	Test Name	Manufacturer
Example: Streptococcus group A	Ace Rapid Strep Test	Acme Corporation

Table from Form CMS-116

Instructions for completion are on Page 6 of the Form CMS-116. If uncertain about any part of the form or requirements, contact the CLIA Agency in your state for clarification or seek guidance from experts experienced in CLIA regulations. Completed CMS-116 applications and associated documentation must be sent to the local State Agency.

TIPS FOR COMPLETING THE CLIA APPLICATION FOR CERTIFICATION FORM

1. Conducting an online search with "[Your State] CLIA application" can help with locating information about CLIA waivers specific to your state. For example, in most states the lab director can be a pharmacist, but there are instances where this is not the case.
2. Pharmacies starting off by offering one or a few POC tests can include the names of additional POC tests that could be offered in the future on their CLIA Application. This prevents the need to submit another CMS-116 form when adding to the tests provided at your site.
3. For CLIA-certified pharmacies adding POC tests that weren't initially included during application submission, another CMS-116 form should be submitted that includes information about the new POC tests being offered.
4. If you intend to conduct testing off-site, this needs to be indicated on the application.
5. Once applications and required documents are submitted to your CLIA state agency, they will provide feedback and guidance if anything needs to be updated or re-submitted.
6. Once the CLIA waiver is approved, you will receive an email notification. The application fee must be paid in order to receive the certificate that is required to update any Medicare enrollment applications.

ARE YOU FROM NEW YORK, WASHINGTON, OR OUTSIDE OF THE U.S. AND ITS TERRITORIES?
New York Limited Service Laboratories certificates required for pharmacies conducting POCT in New York are the equivalent of CLIA certificates in other states. Email or call the New York State Department of Health at (518) 485-5378 for guidance.
Washington Email or call the Washington State Agency at 253-395-6746 for guidance.
International Labs Email the International Laboratory CLIA Certification Process before completing the CMS-116 form.

CLIA RESOURCES

CLIA Waiver Application Form CMS-116
CLIA State Agency Contacts, May 2023
International Laboratory CLIA Certification Process
List of CLIA Waived Tests
List of CLIA Waived Tests + CPT Codes
CLIA: How to obtain a CLIA Certificate of Waiver, March 2019
How to Apply for a CLIA Certificate of Waiver, July 2020
How to update your CLIA Certificate of Waiver, July 2020

SETTING UP YOUR POCT SERVICE

Provide insights into costs associated with POCT, including equipment and training.

BEFORE SETTING UP YOUR SERVICE ASK YOURSELF…

1. Where will POCT take place in the pharmacy?
2. Who will order CLIA-waived tests and ancillary supplies?
3. How will I train pharmacy staff involved with POCT on disease-state education, health assessments, specimen collection, and POCT procedures?
4. How can I best utilize support staff to make this service efficient and sustainable?
5. How will people sign up for POCT services?

YOUR POCT BUSINESS PLAN

As with any new pharmacy service, developing a business plan can help with anticipating challenges, evaluating business readiness to implement POCT, and leveraging strengths to effectively introduce and sustain POCT services. Here are some questions that your POCT business plan aims to answer:

1. **EXECUTIVE SUMMARY**: What are the primary objectives and unique selling points for your POCT service and how will it address the healthcare needs of the community?
2. **DESCRIPTION**: What is the mission and vision for this service and how does this align with the pharmacy's overall mission, history, values, and other services offered? Which type(s) of tests will be offered and what are the unique value propositions?
3. **MARKET ANALYSIS**: Which demographics would benefit most from POCT? Who are your competitors, what gaps exist, and what is the current demand for testing in your community?
4. **OPERATIONS**: What will POCT workflow look like for each staff member involved? What training programs and/or tools will support operational efficiency? Who will supply POCT equipment and who will oversee inventory management and quality control?
5. **REGULATORY & COMPLIANCE**: What steps will be taken to ensure compliance with local, state, and federal POCT regulations? How will you mitigate risks and errors in the testing process?
6. **FINANCIALS**: What are the expected costs (supplies, marketing, training, etc.), revenue projections, and break-even analysis? Which reimbursement methods will be utilized and what is the projected return on investment for each?
7. **ENVIRONMENTAL ANALYSIS/SWOT ANALYSIS**: What internal and external factors can be identified that might affect achieving the goal? What risks are associated and what opportunities exist that might impact the success of a program?

SPACE CONSIDERATIONS FOR POCT IN THE COMMUNITY PHARMACY

The optimal space for point-of-care testing in a pharmacy depends on several factors, including the number of tests offered, the volume of tests performed, and the available physical space within the pharmacy.

Parking lot or curbside testing models can help prevent the spread of infectious disease by keeping potentially contagious patients away from pharmacy staff and patients. Here are some considerations:

1. **DEDICATED AREA:** The POCT area should be separate from the main dispensing area to ensure patient privacy and minimize disruptions. Some states require this separation by law.
2. **PORTABLE POCT STORAGE:** If you do not have the convenience of a dedicated POCT consult room or large counter space, consider a tiered rolling cart, with or without drawers, for testing devices and supplies. This reduces space requirements, while also providing a portable method for testing patients outside of the pharmacy.

3. **SIZE AND LAYOUT:** The size of the area should be adequate to accommodate necessary POCT equipment, supplies, sample collection, and seating for patients. Ensure that proper biohazard disposal containers are available.
4. **PATIENT PRIVACY:** The space should provide sufficient privacy for conducting tests and discussing sensitive results with patients. This may include partitions, curtains, or separate testing rooms.
5. **SAFETY MEASURES:** Ensure quick access to sharps and biohazard disposal containers, personal protective equipment (PPE) storage, and ancillary supplies such as gloves, masks, disinfectants, and other cleaning products.
6. **AESTHETICS:** A clean, organized, and welcoming environment can enhance the patient experience and instill confidence in the quality of care provided.

AVAILABLE POINT-OF-CARE TESTS

Click here to access the FDA's list of CLIA-waived tests by analyte name. This is quite an extensive list, so here are a few tests commonly offered in community pharmacies:

- Blood Glucose
- Influenza A/B
- Strep (Streptococcus, Group A)
- COVID-19
- Respiratory syncytial virus (RSV)
- Hemoglobin A1C
- Lipid Panel (TC, TG, LDL, HDL)
- HIV Antibody
- Hepatitis C
- Urinary Tract Infection (Nitrite, pH, Leukocytes)
- Sexually Transmitted Infections

Due to occasional supply chain issues, it is recommended to have multiple avenues for obtaining tests and ancillary supplies. Pharmacies can consider working directly with one or more manufacturers, manufacturer distributors or wholesalers, medical wholesale supply companies, or mass merchants (including online) to secure regular access to essential POCT supplies.

DID YOU KNOW?

Several pharmacy wholesaler distributors offer POCT add-on services that provide turnkey solutions for POCT services in pharmacies. These solutions can include analyzers, testing supplies, policies and procedures, required documentation templates, PPE, access to education and training on testing equipment, marketing materials, and physician outreach and protocols.

Sofia® 2

Elevating customers to patients with leading test-to-treat tools

- Compact and easy to use with flexible workflows
- Fluorescent technology guarantees an on-screen, objective results you can trust
- A cost-effective solution with a robust test menu, allowing for platform consolidation that optimizes operational efficiencies
- Control your patient data seamlessly with integrated data management options to best fit the needs of your pharmacy

Menu

Flu+SARS Antigen*	RSV
SARS Antigen+	Strep A+
Influenza A+B	Lyme (whole blood)

*This test has not been FDA cleared or approved but has been authorized by the FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. This assay is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless authorization is terminated or revoked sooner.

Virena®

Real-time infectious disease reporting at your fingertips

Sofia 2 comes equipped with Virena, a wireless, cloud-based system that stores de-identified patient test results that are transmitted securely from Sofia 2 daily.

Learn more about Sofia 2 by e-mailing: pharmacy@quidelortho.com or by visiting quidelortho.com.

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AD60028EN Rev. A (12/23)

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Here are some factors to consider when communicating with POCT device manufacturers:

1. **TEST PERFORMANCE:** Test performance data should be reviewed for each device being considered, including the time it takes to run each test, specimen required for testing, sensitivity/ specificity, and positive/ negative predictive value.
2. **PURCHASE PRICE:** Keep in mind that cheaper devices may not always be the best long-term investment if they lack features, accuracy, or reliability. Seek opportunities for price matching, negotiation, and obtaining discounts for purchasing multiple products.
3. **SOFTWARE AND MAINTENANCE:** Some devices use software that integrates with electronic health records (EHR) or pharmacy management systems, streamlining documentation and reporting of results. Inquire about software upgrades and ongoing maintenance requirements and ensure that manufacturers provide regular updates to keep the device software current and compliant with reporting regulations.
4. **SUPPORT AND TRAINING:** Adequate training for pharmacy staff is essential for the proper use of each device. Seek manufacturers that offer responsive customer support and provide comprehensive, ongoing training for your team.
5. **DEVICE REPLACEMENT:** Understand warranty and replacement policies. Determine the expected lifespan of the device and whether it can be easily replaced if it malfunctions.
6. **ANCILLARY SUPPLIES NEEDED:** Calculate the ongoing costs of ancillary supplies required for each device, including specimen collection materials, quality control materials, and disposables. These costs can add up over time and impact your budget for POCT.
7. **MINIMUM ORDERING REQUIREMENTS**: Some POCT suppliers have minimum order requirements which can affect inventory management and turnover rates. In these cases, it may be helpful to collaborate with other pharmacies or healthcare providers in the area to explore group purchasing opportunities or to share orders to meet minimum requirements.

DID YOU KNOW?

QuidelOrtho Corporation can help simplify the start-up of your test-to-treat program by providing two options to get started.

1. **Capital Purchase:** where you purchase the system and test kits and that would be the cost to start the program.
2. **Placement**: where there is no upfront cost to acquire the system and the only startup cost is the kits themselves.

STAFF TRAINING

Each pharmacy staff member involved with point-of-care testing should undergo comprehensive training to ensure the safe and accurate performance of POCT procedures. Staff should be aware of proper procedures for sample collection, test administration, result interpretation, and documentation. They should also be aware of the potential risks associated with inaccurate testing and how to minimize them. Key types of training to consider include:

1. Bloodborne pathogens
2. Device-specific training, including quality control, troubleshooting, and maintenance
3. Infection Control and Hygiene
4. HIPAA Compliance
5. Emergency Response and First Aid
6. Disease-specific training and continuing education

DID YOU KNOW?

QuidelOrtho Corporation has a robust training portal for pharmacy teams to access. Learn at your own pace and fit training in when it is most convenient. If more training is needed, their team of field application specialists can conduct virtual training to answer any questions. Click here to access the Sofia training portal.

STAFF TRAINING RESOURCES

- NASPA Pharmacy-Based Point-of-Care Test & Treat National Certificate Program
- Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens and Needlestick Prevention
- Center for Disease Control and Prevention (CDC) Preventing Healthcare-associated Infections
- CDC Ready? Set? Test! Patient Testing is Important. Get the Right Results

DID YOU KNOW?

QuidelOrtho Corporation offers training videos on how to use their devices. Check out this video explaining how to use the Sofia 2 SARS Antigen+ FIA.

Sofia 2
SARS Antigen+ FIA

QUALITY CONTROL (QC)

Ongoing quality assurance helps to ensure accurate test results over time, thereby safeguarding patient safety and compliance with regulatory standards, like CLIA. Manufacturer inserts for each testing device include instructions for QC, including frequency and what to do when QC values are not acceptable. Note that some states also have requirements for testing frequency, which will override manufacturer guidance. Unfortunately, the simplicity of some POCT devices and other competing priorities may tempt individuals to take shortcuts around performing QC as required.

STAFF INVOLVED WITH POCT SHOULD BE FAMILIAR WITH:

1. Storage requirements for reagents and QC material
2. How to document QC activities and expiration dates for new shipments and lot numbers
   - QC logs should include details like date, time, operator, test results, and any actions taken in response to unacceptable results
3. How to perform QC for each device, and at what frequency
4. How to interpret QC results and how to troubleshoot based on QC results
5. Situations for performing QC outside of regular frequency (e.g. questionable patient results, change in reagent lot numbers, after calibration, etc.)

In addition to QC for POC tests and materials, pharmacy teams should also consider other quality activities, including ongoing training, recertification, and internal audits, at least annually. Regularly reviewing QC logs, procedures and protocols and making improvements based on QC insights will help to continually elevate the quality of your POCT services.

QC RESOURCES AND TEMPLATES

CDC Ready? Set! Test! Quality Control Log - Qualitative Test
CDC Ready? Set! Test! Quality Control Log - Quantitative Test
CDC Ready? Set! Test! Temperature Log

POLICIES AND PROTOCOLS

Implementing POCT in community pharmacies requires staff to pay close attention to detail and enforce rigorous quality control standards to ensure patient safety. In order to do so, overall standard operating procedures (SOP) and disease-state-specific protocols should be developed, reviewed by staff, and kept near POCT equipment. These guidance documents are an important part of any appropriate quality management system.

Standard Operating Procedures (SOPs) will help your team achieve efficiency, quality, and uniformity in workflow while reducing miscommunication and failure to comply with state laws and regulations.

CONSIDER THE FOLLOWING WHEN DEVELOPING POCT STANDARD OPERATING PROCEDURES:

- Clinical significance of each test
- Test administration instructions
- Patient preparation instructions and specimen requirements
- Storage requirements for devices and other supplies needed
- Instructions for equipment maintenance, calibration, quality control, and accuracy
- Protocols for results, errors, and incidents
- Directives for maintaining logs and audit instructions, evaluations and improvements
- Documentation of staff training

Disease-state-specific protocols outline specific guidelines or procedures to follow for the management and/or treatment of a particular medical condition or disease.

CONSIDER THE FOLLOWING WHEN DEVELOPING DISEASE-STATE-SPECIFIC POCT PROTOCOLS:

- Pharmacist authority for ordering and interpreting tests, and acting on test results
- Criteria for testing as denoted by state laws (e.g. age)
- Training and education requirements for pharmacists and key staff involved in workflow
- Patient evaluation instructions (e.g. medical history, chief complaint, medications, vital signs, allergies, symptom onset)
- Exclusion criteria noting conditions and situations that exclude patients from receiving testing or treatment at your pharmacy (e.g. pregnancy, critical vital signs)
- Test device manufacturer information
- Instructions on next steps based on test result(s)
- Authorized medications and OTC treatments recommended based on test outcome
- Patient education considerations (e.g. symptom control, vaccines, quarantine)
- Monitoring and time-based goals for follow-up (e.g. within 36 hours)
- Documentation and notification requirements required by law

DISEASE-STATE SPECIFIC PROTOCOL EXAMPLES

Disease State	Resource	Source
Influenza	Test & Treat Protocol	Kansas State Board of Pharmacy, 2023
Strep A	Test & Treat Protocol	Kentucky Board of Pharmacy
Strep A	Treatment Protocol	Arkansas Dept of Health
HIV	Provider Flip Card	CDC
HIV	POCT result workflow	Biomed Central
Diabetes	A1c Screening workflow	BMJ Open
UTI	Test & Treat Protocol	Kansas State Board of Pharmacy, 2023
Multiple	Collaborative Dispensing Protocol	Next Generation Dx
Multiple	Collaborative Drug Therapy Management Agreement	Pennsylvania Pharmacists Association

APPOINTMENT-BASED MODEL (ABM) VS WALK-IN

Whether point-of-care testing should be offered as a walk-in or by appointment-only depends on various factors, including your pharmacy's capacity, patient preferences, and the specific tests you plan to provide. Both approaches have their advantages and limitations. Here's a breakdown of each:

	Walk-In Service	Appointment-Based Model (ABM)
Advantages	**Convenience**: Walk-in services are convenient for patients who may need immediate testing without the need for an appointment. Patients can decide to get tested on the spot, especially if they suspect an infection or have symptoms. **Flexibility**: Walk-in options are appealing to patients with busy schedules, unable to plan appointments in advance.	**Predictable Workflow**: Appointments allow for better control of patient flow, reducing waiting times and ensuring efficient use of staff resources. Patients can schedule appointments at their convenience, making it easier for your pharmacy to plan ahead. Additionally, offering POCT for chronic disease monitoring and management in alignment with med sync pick-up dates allows for maximum efficiency. **Patient Eligibility:** If billing insurance, collecting patient insurance information in advance can help with verifying patient eligibility and reimbursement before the patient arrives for their appointment.
Limitations	**Patient Wait Times:** Without appointments, there may be peak times when patients have to wait, leading to potential dissatisfaction. Managing patient flow and maintaining social distancing in the pharmacy during peak times can also be a challenge. **Staffing**: Adequate staffing is required to handle walk-in traffic efficiently, especially during peak periods.	**Reduced Convenience:** Patients may be less likely to seek testing if they need to make an appointment in advance, potentially leading to missed opportunities. **Administrative Overhead:** Managing appointments, reminders, and scheduling can require additional administrative effort and technology.

WALK-IN VS ABM – FACTORS TO CONSIDER WHEN DETERMINING WHICH METHOD IS BEST FOR YOU

- **PATIENT PREFERENCE**: Consider the preferences and needs of your patient population.
- **TYPES OF TESTS OFFERED:** The nature of the tests you offer may influence the choice. For routine tests like cholesterol or A1C checks, appointments may work well. For urgent tests like COVID-19, influenza, or strep throat, walk-in options may be essential.
- **PHARMACY SPACE:** Assess your pharmacy's capacity to handle walk-in patients efficiently, including staffing and space availability.
- **SCHEDULING SOFTWARE:** Consider investing in scheduling software or systems that can streamline the intake process, send reminders, and collect payments.
- **COMBINATION**: Some pharmacies offer a combination of both walk-in and appointment-based models. Reserving certain days and/or time slots for appointments while allowing walk-ins during specific hours can help to accommodate varying patient needs.

PATIENT CARE AND EDUCATION

COMMUNICATION BEST PRACTICES

- **Use plain language:** Use concise, easy-to-understand language when explaining the testing process, the purpose of the test, and what the results mean for the patient's health. For positive results, educate on self-isolation and care steps. For negative results, emphasize preventive measures and symptom monitoring.
- **Cultural Competency:** Be aware of cultural norms, values, and beliefs that may influence healthcare decisions. This will help to foster an inclusive environment that respects diversity and welcomes all patients.
- **Treatment options:** Discuss available self-care and prescription treatment options, if applicable. Provide information on next steps, including referrals to healthcare providers and follow-up.

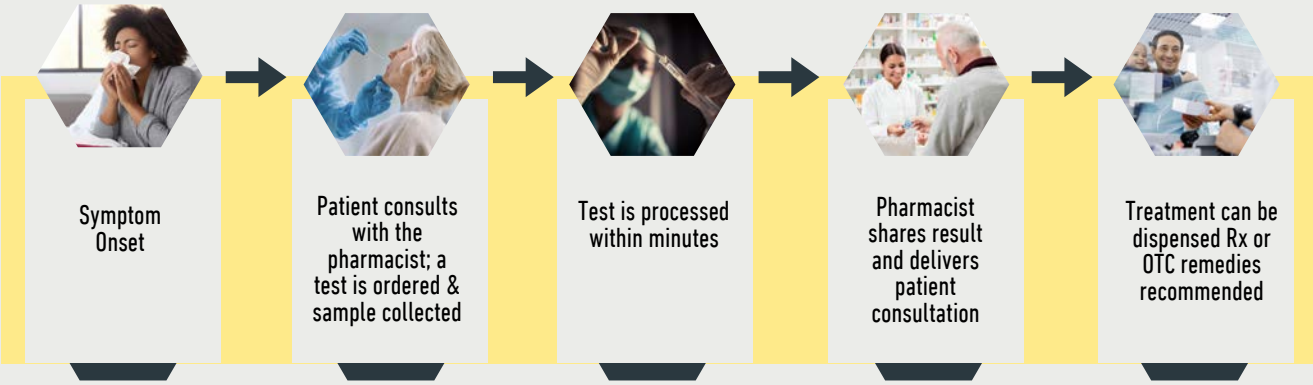
INFECTION CONTROL PRACTICES

- Consider wearing protective personal equipment (PPE), such as gloves and face masks. Wearing PPE may also instill confidence in patients regarding the safety and quality of testing services offered.
- Change gloves and wash or sanitize hands between specimen collections.
- Decontaminate instruments used during testing according to manufacturer instructions.
- Handle all fluids as if they're infectious and all laboratory waste as biohazardous waste.
- Consider partnering with a medical waste disposal company to collect biohazardous waste.

RESOURCES

CDC Self-Assessment Checklist for Good Testing Practices
CDC Ready? Set! Test!

POCT WORKFLOW



Efficient workflow management is crucial to ensuring accurate results, patient safety, and a seamless experience. By implementing these strategies below and emphasizing a culture of safety and continuous improvement, pharmacies can optimize POCT workflows, reduce errors, and deliver high-quality patient care.

- Develop clear and standardized protocols for each type of point-of-care test offered. These protocols should walk through the entire process from patient intake and sample collection to result interpretation and reporting.
- Keep copies of manufacturer device instructions on hand for easy reference.

- One swab, one patient, one basket, one timer – to reduce errors, use pharmacy prescription labels to identify the patient, date of birth, date of specimen, and specimen type. Use a standardized labeling and/or basket color system to minimize the risk of sample mix-ups.
- Integrate POCT results into the pharmacy's dispensing software or patient management system to maintain comprehensive and up-to-date patient records.

SUPPORT STAFF VS PHARMACIST ROLES

Efficient delegation of tasks between pharmacists and support staff can help optimize workflow and reduce the overall costs of delivering POCT in the pharmacy. By clearly defining roles and responsibilities, pharmacies can make the most of both pharmacist and support staff expertise.

Here are POCT roles that non-pharmacist support staff can oversee, allowing pharmacists to focus on tasks that require clinical decision-making, patient consultation, and treatment recommendations:

- CLIA Certificate of Waiver application
- Patient scheduling, intake, and check-in
- Specimen collection and sample processing
- Equipment setup, quality control, and maintenance
- Test administration, clean-up, and disposal
- Documentation and reporting to state agencies
- Inventory management
- Insurance billing and reconciliati

DOCUMENTATION, RESULTS, AND REPORTING

DOCUMENTATION

Pharmacies must maintain accurate records of test results, including patient information, specific test information (including lot numbers and expiration dates), results, proof of reporting, and any follow-up actions recommended or taken. Detailed documentation supports quality assurance and helps track patient progress over time.

RESULTS

In addition to providing patients with quick access to results and recommendations for self-care and/or infection control, results should also be shared with each patient's primary care provider, if they have one. Faxing providers and informing them of why testing was indicated, results, actions taken, and any prescriptions needed, can help with continuity of care. These prescriber notifications also present opportunities to increase awareness of the POCT services in your community.

REPORTING REQUIREMENTS

Different jurisdictions have strict requirements governing the reporting of POCT results. Some state and local health departments mandate the reporting of certain infectious diseases or conditions. Pharmacists conducting POCT should familiarize themselves with local regulations and timelines for reporting positive or notifiable results to the appropriate health authorities. Adhering to designated reporting timelines ensures that necessary public health measures can be taken promptly.

Establishing systems for the integration of POCT results into pharmacy management software can ensure seamless data transfer while maintaining accuracy and security. Integrating results from the pharmacy management software to required reporting databases streamlines access to information for other healthcare providers, supports continuity of care, and helps maintain compliance with reporting requirements.

DID YOU KNOW?

The Sofia 2 Analyzer for SARS can be connected to reporting systems, enabling automated result transmission, and eliminating transcription errors.

Additionally, it can connect to pharmacy workflow automation software digitizing the patient intake process and streamlining the diagnostic workflow for pharmacists.

Add in the power of Virena and you have a complete data management package.

MARKETING YOUR POCT SERVICE

Proper marketing and public awareness campaigns are necessary in order to inform the public about the availability of these services at your pharmacy. Identifying potential collaborators, referral sources, and target markets is a good place to start.

BEFORE MARKETING YOUR POCT SERVICE ASK YOURSELF…

- What services are local competitors providing?
- What sets my POCT service apart from competitors in my area?
- What is my target market? What specific demographics or patient groups will benefit most?
- Will I focus on social media, email and SMS marketing, local events, or a combination?
- What metrics will determine the success and ROI of marketing activities?

MARKETING STRATEGIES:

- Consider hiring an **independent marketing consultant** or expert to brainstorm, create, and publish compelling marketing content.
- **Always** encourage POCT patients to leave positive reviews online.
- **Pharmacy support staff** should be encouraged to provide information to patients and customers about the availability of POCT, especially when patients present with certain symptoms. "While you're here, how about we test you for flu or strep? It will only take 15 minutes."
- **Use bag tags, flyers, IVR and SMS messages, and in-store signage** to market to regular patients who already trust the pharmacy for their healthcare needs. Use text messages and fax signatures to promote your services to patients, customers, and prescribers.
- **Host educational workshops** or tabling sessions in the pharmacy, or online, to facilitate discussions about the benefits and availability of POCT to current customers.

KEY PARTNERSHIPS:

- **Local chambers of commerce and other civic organizations** can provide networking platforms to connect with community leaders and other business owners. Be sure to have your POCT 'elevator pitch' ready when attending these events.
- **Local health departments** can help with data collection, reporting, and community outreach for POCT services.
- **Community clinics and hospitals** can serve as partners in patient care, especially in the follow-up of positive test results.
- **Local newspapers, radio stations, or TV channels** are often eager to partner with local community pharmacies for informational segments about prevalent infectious diseases and chronic disease management. This is a great time to educate the public while promoting POCT services available at your pharmacy.
- **Business coalitions of health** are coalitions of employers using their collective voice, along with other healthcare stakeholders, to impact the quality and cost of healthcare delivery systems.
- **Telemedicine companies** can be important referral resources for pharmacies unable to provide treatment upon positive test results. This provides a way for pharmacists to connect patients with providers when a positive test result requires further medical attention or prescriptions.

TIPS FROM YOUR PEERS

"Physician 360 has been the primary partnership we've utilized for treatment. We were never able to fully pursue or utilize a collaborative practice agreement and those differ in scope based on state laws. While Physician 360 is an additional fee, it can still be cheaper than the cost of an office visit.

One of the biggest barriers to using telehealth is the technology component. Had we more fully pursued a true test-and-treat model, we would have utilized on-site technology to overcome this barrier."

Garrett Sipes, PharmD
Pharmacist
Keystone Pharmacy, Chambersburg, PA

REFERRAL SOURCES: Notify local healthcare providers and other professionals, including community agencies and service organizations about the POCT services you offer so they can be a source for potential referrals.

- **Physicians' offices and urgent care centers** can refer their patients to pharmacies for convenient and rapid testing outside of normal business hours or during times of oversaturation. Visit prescribers' offices to inform them about POCT services, the benefits of collaboration, and how POCT can enhance patient care.
- **Nursing homes and assisted living facilities** may seek on-site POCT services for their residents, especially for regular health checks or infectious disease screenings. Consider arranging informational sessions or demos for these types of facilities.
- **Local employers and companies** might be interested in chronic disease screenings for their employees, like diabetes or hepatitis C, that might present cost-savings in the long run, especially for self-insured employers.
- **Community centers and fitness centers** are potential venues for health fairs and advertisements where your pharmacy can showcase POCT and related health screenings. Consider offering free or discounted screenings during community events to attract potential patients and customers.

MARKETING MESSAGING: Marketing messaging should lead with the benefits of POCT services at your pharmacy, including fast results, convenient location, extended hours, and immediate treatment (if applicable).

- **Student pharmacists** can develop and publish blog posts on your pharmacy website related to the different types of POCT services offered. This way, when potential customers search online for POCT services in their area, they will come across your pharmacy's blog article and learn more about the POCT services you offer.
- **Diagnostic manufacturers** can provide access to customizable marketing materials.
- Share **success stories or case studies** highlighting positive patient outcomes or experiences with POCT.

EXAMPLE MARKETING MESSAGING

1. **GENERAL PROMOTION:** Get quick answers to your health concerns with our COVID and Flu testing! Rapid results, same-day appointments, and expert care—all at your convenience. You'll see just how efficient healthcare can be at ____ Pharmacy. #COVIDTest #FluTest
2. **SEASONAL HEALTH AWARENESS:** Flu season is here, but you don't have to wait too long for answers if you're feeling under the weather. Our pharmacy offers rapid flu testing with results in minutes! Stay healthy and keep your family flu-free this season. #FluSeason #POCT
3. **COVID-19 TESTING:** Your health matters, and so does your peace of mind. Our pharmacy provides quick and accurate COVID-19 testing. Know your status in no time. Visit our website and schedule your test now. #COVID #COVIDTest
4. **CONVENIENCE FOCUS:** We understand your busy schedule. That's why we offer testing for COVID and Flu with no appointment needed. Walk in and walk out with answers. It's healthcare on your terms! #Testing #COVID #Flu
5. **EDUCATIONAL CONTENT:** Do you know the benefits of quick testing for Flu and Strep? Getting quick results when feeling sick helps you to make informed decisions about your health. Learn more on our website. #StrepTest #FluTest
6. **HEALTH TIPS:** Stay proactive about your health this year! Regular check-ups, in addition to regular blood sugar and cholesterol testing, can help you catch issues early. Take charge of your wellness journey and get tested at _____ Pharmacy today. #WellnessWednesday #DiabetesTesting #HIVTesting #A1C #Cholesterol
7. **SPECIAL PROMOTIONS:** Limited-time offer: ____ Pharmacy is offering FREE blood sugar, blood pressure, and cholesterol screenings this Saturday from noon to 3pm! Don't miss this opportunity to prioritize your health and know your status. Book your slot now. #HealthScreenings #healthylifestyle
8. **COMMUNITY INVOLVEMENT:** We're proud to be part of the _____ community. Join us this weekend for a health fair featuring free Point-of-Care Testing. We'll be checking blood pressure, blood sugar, and cholesterol. Together, we can promote wellness! #CommunityHealth

Consistency and authentic engagement are key to building trust and credibility as a reliable POCT site. A combination of these marketing and outreach strategies will help you effectively raise awareness about your POCT services and foster collaborations with key community partners.

DID YOU KNOW?

The NASPA Pharmacy-based Point-of-Care Test & Treat National Certificate Program provides an opportunity to gain the skills and information necessary to develop a testing program such as influenza, Group A Streptococcus, HIV, Hepatitis C, coronaviruses, and chronic diseases.

The 20-hour ACPE-accredited certificate program includes comprehensive material regarding key disease states, physical assessment, point-of-care tests and treatment, and business models.

NASPA Pharmacy-Based Point-of-Care Test & Treat
National Certificate Program

POCT REIMBURSEMENT MODELS

CASH-PAY

Cash-pay pricing for POCT services in a pharmacy can be a valuable addition to your business model. By carefully considering costs, competition, and patient needs, you can offer accessible, affordable, and profitable healthcare solutions while maintaining your pharmacy's financial health. Note: If you are enrolled with Medicare as an Independent Clinical Laboratory then a Cash Reimbursement Model for their Medicare patients is NOT allowed.

It is a common myth that patients always prefer services billed to their insurance. Most patients are willing to pay out of pocket for convenience and efficiency. Keep in mind that your pharmacy cash price for POCT services might be the same or even less than what a patient's copay would be when visiting their primary care provider or urgent care.

Additionally, health savings accounts (HSAs) and flexible spending accounts (FSAs) benefit coordinators consider most lab testing to be a qualified medical expense. This allows patients with these benefits to pay for POC tests using HSA/FSA funds.

Considerations before pricing for cash-pay:

1. MARKET ANALYSIS

- **Local Competitors:** Analyze the pricing strategies of local competitors, including urgent care centers, doctor's offices, and other pharmacies offering similar services. You can cold call and inquire about prices or conduct research online.
- **Patient Demand:** Ask current patients and customers in person or via SMS messaging about interest and demand for different types of POCT services in your community.

2. COST ANALYSIS

- **Calculate** direct and indirect costs associated with each point-of-care test to ensure your cash pay price covers these costs while leaving room for profit.
- **Direct**: Test kits, ancillary supplies (band-aids, cotton swabs), staff time
- **Indirect**: space, equipment, training

Example POCT Costs - *these costs are estimates/examples and are provided for information purposes only.*	
POCT instrument/analyzer	$300 - $1,500
Placement of instrument	$0
Estimated costs per individual test	
Flu test	$15.00
Strep A test	$4.50
COVID-19	$20
Flu + COVID	$25
A1c test	$15
HIV test	$15

INSURANCE REIMBURSEMENT

Billing patients' medical insurance for pharmacy-based POCT can be a complex yet financially rewarding process. Specific billing codes can vary based on the test being conducted and the payer. For Medicare and Medicaid patients, CMS has specific reimbursement rates for CLIA-waived tests. If contracted and credentialed to do so, Medicare and Medicaid mandate that providers bill and accept the allowed reimbursement for all laboratory tests.

Credentialing and contracting with payers to bill the medical benefit are essential steps for pharmacies looking to receive reimbursement for POCT services from payers. This process can be challenging and time-consuming. Additionally, each payer has its own unique requirements and processes. Therefore, it's essential to maintain open communication with payer representatives and follow their guidance throughout the credentialing process.

Pharmacies can also seek assistance from healthcare consulting firms or credentialing services that specialize in helping providers navigate the credentialing and contracting process with various payers. These services can streamline the process and help ensure successful credentialing.

GETTING STARTED…

1. To bill Medicare, you will first need to work with your designated Medicare Administrative Contractor (MAC) to enroll as an Independent Clinical Laboratory by submitting a Medicare enrollment application (Form 855B or 855I). For pharmacies that already have a PTAN, you will get an additional PTAN.
2. Ensure that your pharmacy's taxonomy code in the NPI NPPES Registry reflects clinical laboratory status, as this is essential for accurate billing.
3. Being contracted with payers to provide POCT, not only as a pharmacy but also as a medical lab, may be required for certain billing processes. Note that some plans do not require in-network status in order to bill and receive payment.
4. Set up the necessary billing infrastructure, including access to billing intermediaries (i.e. Electronic Billing Services (EBS), Omnisys, etc.), software vendors (i.e. Signetic, Intend, etc), and/or clearinghouses (i.e. Office Ally, Availity, etc.) for third-party billing.
5. Understanding the types of insurance plans (HMO, PPO, EPO, POS) and covered benefits under each is essential. It helps to be familiar with different payers and plans, checking eligibility and understanding the responses.

REMINDER

Enrollment with Medicare requires your CLIA waiver certificate and CLIA certification must be renewed every two years. Medicare enrollment requires updates to be made within 30 days. Therefore, you must update your Medicare enrollment with the updated certificate within 30 days prior to or 30 days after your certificate expiration date. Failure to do so could lead to a revocation of your Medicare billing privileges.

INSURANCE REIMBURSEMENT CONSIDERATIONS

- **PLACE OF SERVICE CODES:** Different codes correspond to various healthcare settings, and selecting the appropriate one for each specific scenario can greatly impact claims processing and reimbursement. Pharmacy teams should remain vigilant about entering the most suitable place of service codes for different situations. Whether it's an encounter at the pharmacy (code 01) or a home visit (code 12), using these codes correctly is essential for proper reimbursement.
- **EDI COMMUNICATION PROCESS FOR HEALTHCARE BILLING:** Electronic Data Interchange (EDI) is the electronic exchange of healthcare information between providers (in this case, pharmacies offering POCT services) and payers.
- **PAYOR PARITY AND SCOPE OF PRACTICE:** The ability to bill for certain POCT-related services is contingent on state scope of practice and state insurance laws. Just because a billing company might offer a solution for you to be able to bill for a service, it doesn't mean that you are legally allowed to provide that service. For example, pharmacists can only bill for E/M (evaluation and management) services if their state's scope of practice and insurance laws permit it. Note: Medicare does not currently allow pharmacists to bill for E/M services. Payor parity laws come into play in ensuring that pharmacists receive fair reimbursement for their services, and these laws can vary from state to state.
- **PATIENT ELIGIBILITY AND PLAN STRUCTURE:** It is important to understand how insurance companies structure their plans, such as HMO vs. PPO, and how these plan differences can affect patient access and copays.

CONTRACTING AND CREDENTIALING

The contracting and credentialing process can vary depending on the insurance companies you intend to work with.

Contracting refers to the process by which a pharmacy enters into an agreement or contract with a health insurance plan, managed care organization, or other third-party payer to establish a formal relationship, outlining the terms and conditions under which the pharmacy will provide services and be reimbursed.

Credentialing is a process that focuses on verifying and assessing the qualifications, credentials, and eligibility of healthcare providers to participate in a payer's network. Each pharmacist, practitioner, and/or clinician needs to have their own National Provider Identifier (NPI).

In summary, contracting formalizes the relationship between the pharmacy and the payer, outlining terms for service provision and reimbursement, while credentialing focuses on individual practitioners. While in-network contracting is common, sometimes pharmacies might find higher reimbursement rates by remaining out of network.

DID YOU KNOW?

Just because your pharmacy is contracted with an insurance company does not mean that you are automatically in-network for ALL of the various plans the payer offers. You must contract with each plan!

For instance, take two patients both covered under the payer, United Healthcare, but one has an HMO plan and the other a PPO plan. Even though these plans are with the same payer, there are differences that can be expected regarding coverage and patient responsibilities for copays based on their in-network or out-of-network benefits and whether you (as the provider) are in or out of network with their plan for that payer.

Here is a general outline of the steps involved in contracting with health plans:

1. **IDENTIFY TARGET HEALTH PLANS:** Determine which insurance companies you want to work with. This could include Medicare, Medicaid, private insurance providers, and any other relevant payers.
2. **CONTACT PAYER REPRESENTATIVES:** Reach out to the provider relations or network contracting departments of the selected payers. You can usually find contact information on their official websites.
3. **COMPLETE CREDENTIALING APPLICATIONS:** Credentialing applications should be completed for each pharmacist/clinician working in your organization. Be prepared to submit supporting documents, such as proof of licensure, certificates, and any required certifications. Some payers may require electronic submissions, while others may accept physical paperwork. Any omissions can significantly delay the credentialing process.
4. **REQUEST TO JOIN AS A LABORATORY:** Once the credentialing application is complete, proceed to the "Provider" section of the payer website and search for "Join the Network." You will want to complete the process as an "Ancillary Provider" to join as a "Laboratory."
5. **NETWORK SUFFICIENCY:** Once the steps to credential and request to be an in-network provider are complete, the plan will review your request and determine if they need you in their network. They will review and compare the services you plan to provide to the services already provided by other in-network providers in your area.
    a. If they determine they already have enough providers in your area, providing the same services, they will likely send a rejection letter, declining your request.
    b. If you receive an approval, then the contract/negotiation phase begins.
6. **CONTRACTING AND NEGOTIATION:** The approval process takes time, often several weeks or even months, depending on the health plan. Health plans will verify the information provided in your application, and then initiate contract negotiation. Carefully review the terms of the agreement, paying close attention to claims filing time limits, reimbursements, plans included, and product categories allowed under the agreement.
    a. If you agree, proceed to signing and executing the agreement.
    b. If you do not agree, contact the account representative assigned to you to negotiate the terms of the agreement.
7. **BILLING AND CLAIMS SUBMISSION:** Once contracting is complete and contracts are in place, you can start providing POCT services to eligible patients. Ensure that documentation and claims submission processes comply with the terms of the contracts.
8. **STAFF EDUCATION:** Train pharmacy staff on specific requirements and procedures for billing and claims submission for each health plan you are contracted with.

DID YOU KNOW?

If you receive a rejection from a health plan, you can find out who is in-network in your area, what services they provide, and how you are different from them.

Once this information is gathered, pharmacies can submit a reconsideration request strongly assuring the payer of their need for your pharmacy to be in-network, the benefits to their members, and the savings to their plan.

If denied a network contract, there are still opportunities to bill as an out-of-network provider, but not all patient benefits include out-of-network coverage. If included, it's important to know what the patient's out-of-pocket costs would be when services are rendered by an out-of-network provider.

INSURANCE BILLING RESOURCES

List of CLIA-Waived Tests + CPT Codes

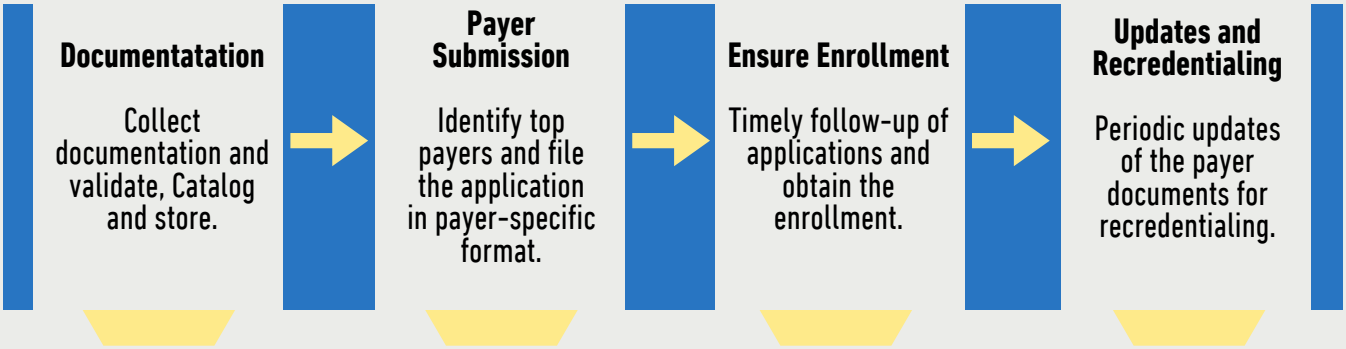
Medicare Enrollment Application

- CMS-855I - For sole-proprietors or single-member limited liability companies (LLCs)
- CMS-855B - For corporations

List of Medicare Administrative Contractors (MACs) (as of June 2019)

CMS Place of Service Codes

PROVIDER ENROLLMENT AND CREDENTIALING



EVALUATION AND MANAGEMENT (E/M) BILLING

Evaluation and Management (E/M) billing is a coding and reimbursement process used by healthcare providers, including pharmacies, to bill for patient visits and consultations. E/M billing allows healthcare providers to document the complexity of patient encounters and receive reimbursement from payers, not including Medicare, for their services. For example, certain pharmacies may be able to bill for blood pressure screenings and patient counseling included as part of their POCT workflow.

REMINDER

The ability to **provide** Evaluation and Management services (aka an office visit code) is based on the Pharmacist state scope of practice laws.

The ability to **bill** for these services is based on the payers acceptance and implementation of those laws.

The ability to get **reimbursed** is based on the patient's plan and your enrollment with that payer.

Not all billing intermediary companies allow for E/M Billing, so always check with your billing provider about the ability to bill for E/M in addition to the POC test and administration.

Here's how E/M billing works for pharmacies:

1. **STATE SCOPE OF PRACTICE AND INSURANCE/PAYMENT PARITY:** Before pharmacies can bill for E/M services, they must check to ensure this is allowed based on their state scope of practice and/or their state insurance laws (and Medicare and Medicaid) mandating payment parity.
2. **PROVIDER CONTRACTING AND CREDENTIALING:** Going through the contracting and credentialing process allows pharmacies to become recognized as healthcare providers by payers.
3. **PATIENT ENCOUNTERS:** When a patient visits the pharmacy for a clinical service that involves an evaluation and management component (such as disease monitoring or patient counseling), the healthcare provider conducts the evaluation and management of the patient's condition.
4. **DOCUMENTATION:** The provider documents the details of the encounter, including patient demographics, chief complaint, medical history, review of systems, physical examination, complexity of medical decision-making, diagnosis, and plan of care.
5. **CPT CODES:** The provider assigns Current Procedural Terminology (CPT) codes that correspond to the level of service provided, including the complexity and extent of the patient encounter. These codes are used to classify and bill for the E/M service.
6. **ICD CODING:** In addition to CPT codes, International Classification of Diseases (ICD) diagnosis codes are assigned that describe the patient's condition. These codes provide context for the medical necessity of the services provided.
7. **CLAIM SUBMISSION:** The provider submits a claim to the patient's insurance company or payer, including the CPT and ICD-10 codes, along with the documentation supporting the billed services.

INSURANCE CLAIM RECONCILIATION

Claim reconciliation is a critical process in healthcare billing and revenue management. This involves comparing claims submitted to insurance providers with payments received and resolving any discrepancies or issues. Claim reconciliation is an ongoing process, and pharmacies should allocate dedicated time and resources to manage it effectively.

Here are steps important for claim reconciliation for pharmacies providing POCT:

1. **COLLECT PATIENT INFORMATION:** Ensure that you accurately collect patient information during the intake process, including full contact information and clear photocopies of insurance cards (front and back). Prefixes, the letters in front of the patient ID number, that are generally not used when billing prescription plans are required for medical plans to process these claims.
2. **SUBMIT ACCURATE CLAIMS:** Submit claims for POCT services promptly and accurately. Double-check that all required information is included, such as patient demographics, insurance information, diagnosis codes (ICD-10 codes), procedure codes (CPT or HCPCS codes), modifiers, proper place of service codes, taxonomy codes, and any other necessary documentation.
3. **TRACK CLAIMS SUBMISSION:** Maintain a record of all claims submitted, including the date of submission, the insurance provider, and the claim details. This information will serve as a reference for reconciliation.
4. **MONITOR CLAIM PROCESSING:** Regularly check the status of submitted claims through the clearinghouse or health plan insurance provider's online portal or by contacting their customer service to ensure that claims are being processed.
5. **REVIEW EXPLANATION OF BENEFITS (EOB):** Insurance providers will send an Explanation of Benefits (EOB) for each processed claim. EOBs detail the services billed, the allowed amount, patient responsibility (e.g., copayment, deductible, or coinsurance), and the amount paid by the insurance. Always collect and review EOBs for accuracy.
6. **COMPARE EOBS TO CLAIMS:** Match each EOB received to the corresponding claim submitted. Verify that the information on the EOB aligns with what you billed. Ensure that the payment matches the expected reimbursement.

7. **IDENTIFY DISCREPANCIES:** If you identify discrepancies, such as denied claims, underpayments, or coding errors, investigate the issue to determine the cause. Common reasons for discrepancies include incorrect coding, missing information, or eligibility issues.
8. **APPEAL DENIED CLAIMS:** If a claim is denied, review the denial reason provided by the insurance company. If you believe the denial is incorrect or unjustified, file an appeal following the insurer's guidelines. This may involve submitting additional documentation or correcting errors.
9. **FOLLOW UP ON UNPAID CLAIMS:** For claims that remain unpaid or partially paid, follow up with the insurance company to inquire about the status and reasons for non-payment. Resubmit corrected claims as needed.
10. **PATIENT BILLING:** After reconciling claims with insurance providers, generate patient bills for any remaining patient responsibility, such as copayments, deductibles, or coinsurance. Send clear and concise statements to patients and provide them with payment options.
11. **MAINTAIN RECORDS:** Keep detailed records of all claim reconciliation activities, including communication with insurance providers, appeals, and patient billing. These records are essential for tracking the financial health of your pharmacy's POCT services.
12. **REGULAR RECONCILIATION AUDITS:** Implement regular reconciliation audits to ensure that all claims are processed correctly, and that reimbursement is maximized. Identify trends or recurring issues and take corrective action.
13. **TRAINING AND EDUCATION:** Train key staff on proper claim submission, reconciliation procedures, and coding accuracy. Regularly update them on changes in billing and coding guidelines as issues are uncovered and resolved.
14. **UTILIZE BILLING SOFTWARE AND TOOLS:** Consider using billing and practice management software or services that can automate parts of the reconciliation process and help identify potential issues.

This guide provides general guidance for implementing POCT services in a pharmacy. It is essential to consult with legal and regulatory experts in your state and seek specific advice from relevant authorities to ensure compliance with all applicable laws.

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Appendix A

CLICK HERE FOR A WORD VERSION OF THE SAMPLE INFLUENZA TESTING PROTOCOL

SAMPLE INFLUENZA TESTING PROTOCOL

BACKGROUND AND PURPOSE
Influenza A and B are common viral pathogens causing millions of cases of acute influenza each year. They also lead to thousands of deaths, hospitalizations, missed workdays, and more. Treatment for influenza includes symptom management and, when appropriate, antiviral therapy. These antiviral therapies are indicated only if able to be started within 48 hours of symptom onset. Due to the short window of opportunity for antiviral therapy, quick access to testing and diagnosis is critical. As a CLIA-waived facility, we can provide easy access to waived influenza testing for those at low risk of complications from the flu.

This document details the protocol staff will follow in each instance where we provide an influenza test to a patient.

Training: [Name] is certified by [Training/Accrediting Body] in Point of Care Testing for the Community Pharmacist. [Name] will be responsible for the appropriate training of [Pharmacy Name] staff. Training attestations are at the end of this protocol.

Tests: [Manufacturer, Name of Test] [Lot Number] [Expiration Date]
We will use the test listed above to process all influenza tests collected via this protocol. All manufacturer instructions will be followed in accordance with CLIA. Individual test lot and expiration numbers will be recorded on the patient intake form for quality assurance.

Patient Flow: Presentation > Data Entry > Assessment > Testing > Results

Presentation: Upon initial presentation to the pharmacy, the patient will be greeted as is usual practice. If he or she asks specifically for an influenza test, the patient will be directed to the closed-door counseling room, informed about the cost of the test and of the process for being tested, and instructed to start working on the patient intake and assessment form included at the end of this document. If the closed-door counseling room is currently in use, the patient will be seated in the waiting area and provided the same information and patient intake and assessment form.

In the case where the patient does not directly ask for an influenza test, but a pharmacist or pharmacy team member recognizes the patient may benefit from a rapid influenza test, the pharmacist will quickly explain the ability to provide a test in real-time, the cost of the test, and the process for being tested. If the patient is interested in the test, they will be directed to the closed-door counseling room and asked to complete the patient information section of the intake and assessment form.

Data Entry: Upon completion of the patient intake and assessment form, a copy will be made and given to the data entry technician for entry into [pharmacy dispensing software]. Data entry may include a new patient profile if the patient is new to the pharmacy or simply billing or the influenza test. The test will be billed with the patient's name, the pharmacist completing the test as the provider, the UPC number of the test [insert UPC number], origin code of ___, and a $___ cost. [Insert billing instructions for cash pay or insurance]

Patient Assessment: Upon completion of the patient information section of the intake and assessment form and delivery of the copy of the form to the data entry technician, the pharmacist or pharmacy intern will assess the patient, documenting assessment on the pharmacist section of the intake and assessment form.

This assessment will include:

- Blood pressure as measured by [name of device]
- Pulse as measured by [name of device]
- Respiratory rate
- Temperature as measured by [name of device]
- Oxygen saturation as measured by [name of device]
- Clinical presentation
- Review of symptoms documented by the patient
- Start date/time of symptoms
- Drug allergies documented by the patient
- Current medications documented by the patient
- Current influenza activity in the area

Following this assessment, the pharmacist (if assessment is completed by the pharmacy intern the intern will report out on the patient to the pharmacist at this point) will determine patient eligibility for testing based on the algorithm on the intake and assessment form. If the patient is eligible for a test, the pharmacist will complete the specimen collection and begin the test. The patient may opt to wait in the consultation room or roam the pharmacy as they desire while the test is being completed. Once the test is completed the pharmacist will document the test results on the assessment form and will discuss the results and next steps with the patient.

TEST RESULTS

Positive Results: A positive influenza test indicates a patient should receive antiviral therapy. With the patient's permission and desire, a prescription will be obtained for said therapy.

If a patient is associated with a provider with whom _____ Pharmacy has a collaborative practice agreement, a prescription for the anti-viral therapy will be created by the pharmacist per this agreement. Prescriptions may also be created for prophylactic reasons per this agreement. Per these agreements, patient intake and assessment forms will be faxed to the provider in a timely fashion (by the end of the business day) for their records and review. These prescriptions will be filled with the pharmacist as the prescriber, an origin code of __, and billed to the patient's insurance as appropriate. The prescription of record will be written on a telephone prescription pad, signed by the pharmacist completing the test, and attached to a copy of the patient intake and assessment form before filing.

If the patient is not associated with a provider with whom _____ Pharmacy has a collaborative practice agreement, the pharmacist will contact the office of the patient's primary care physician and request a prescription for an antiviral medication based on the assessment and test results completed by the pharmacist. We will fax a copy of the patient intake and assessment form to the provider for their review and records. If a prescription for ant-viral therapy is not immediately expected back from the provider, the pharmacy will offer to call the patient when the prescription is ready for pick-up or to deliver the prescription to the patient when it is ready. If a patient presents outside of regular business hours for their prescriber or does not have a primary care provider, the patient will be encouraged to use an online telemedicine service or take a copy of their intake and assessment form to a local urgent care center where a prescriber can prescribe antiviral therapy.

Regardless of the anti-viral prescription availability and methodology, patients will also be counseled on over-the-counter products and recommendations for symptom management, infection control, and what to look for as signs of improvement and disease progression.

The testing algorithm should maximize the positive predictive value of the testing, but false positives are, of

course, a possibility. The follow-up component of this program is designed to identify and treat false-positives.

Negative Results: A negative influenza test most likely means the patient has a different, self-limiting viral infection that will likely resolve more quickly and with less severe risks than influenza. Using this assumption and the algorithm that maximizes the negative predictive value of the test, recommendations will include symptom management with information for what to watch for regarding disease worsening or improving. The follow-up component of this program is designed to identify and treat false negatives.

The results of negative tests will also be faxed to the patient's primary care provider for their review and records.

Completing the Transaction and Finishing Steps: Following test result discussion, recommendations for OTC products, and provision of prescription medication (if applicable), the pharmacist will advise the patient to look forward to a follow-up call in 48 hours before sending them to the front register and home.

Following the patient leaving the room, the room will be cleaned prior to the next patient entering the room.

Follow-Up: If not yet completed, the patient intake and assessment form will be faxed to the patient's primary care provider with a cover sheet explaining why the information is being sent. The form will then be put in the dated trays near the data entry technician station for two days following the visit. Each morning, the data entry technician will give forms in that day's basket to the pharmacist for follow-up calls. These calls should be completed before noon and attempted at least twice. The purpose of these follow-up calls is to assess the patient's condition and evaluate progression and/or need for referral to another care provider. Documentation of follow-up calls should be completed on the patient intake and assessment form.

If the patient is progressing well and does not require further follow-up, the completed intake and assessment form may be filed. If the pharmacist believes the patient would benefit from another follow-up call, the form should be returned to the dated bin for the appropriate day.

STAFF TRAINING ATTESTATION

I attest that I was trained on the delivery of point-of-care testing services in a community pharmacy satisfactorily, all of my questions were answered by [Pharmacist name] and I will comply with the contents of this protocol in the care of our patients.

Name	Date

PATIENT INTAKE AND ASSESSMENT FORM

[Pharmacy Name and Address] [Date Revised]

Patient Name: _____Gender: _____ DOB: _____

Patient Address: _____City/State/Zip: _____

Patient Phone Number: (____) _____-_____

Primary Care Physician: _____ Address: _____

Medication Allergies: _____

Current Medications: _____

_____

Past Medical History: _____

_____

Current Situation – When did your symptoms start? _____

Which of these do you currently have?

Fever: Y / N if yes, what temperature? _____

Headache: Y / N

Muscle Pain: Y / N

Sore Throat: Y / N

Runny Nose: Y / N

Cough: Y / N

Fatigue: Y / N

Head/Nasal Congestion: Y / N

Any other symptoms? _____

Have you taken any medications for these symptoms? Y / N

If yes, what and when? _____

Did you get a flu shot this year? Y / N

Are you a current smoker? Y / N

Any other recent medical concerns? Y / N

If yes, please describe: _____

_____

Pharmacy to Complete below this line.

Date: _____ Time Assessment Began: _____ Pharmacist Initials: _____

Referral Source: _____ Influenza Activity (if applicable): _____

First – Review patient information for completeness. Ask to fill in any gaps as needed.

Second – Look for any immediate 'rule outs.' If present, stop, explain, refer out for treatment.

Age: <15 or >80 years

Lung Cancer, Recent Pneumonia, Recent Hospitalization (< 30 days), Severe Lung Disease

If for sure no fever or complaint of feeling feverish, not strep or flu

Symptoms longer than 72 hours

Third – If you made it here, start clinical assessment.

CLINICAL ASSESSMENT

Blood Pressure: _____ /_____ If over 180/100, stop. Refer out for immediate treatment.

Pulse: ____ If over 100 bpm, stop. Refer out for immediate treatment.

Respiratory Rate/Description: _____

Temperature: _____ If more than 103° F (untreated), stop. Refer for immediate treatment.

Pulse Ox: _____ If under 90%, stop. Refer out for immediate treatment.

Tonsils: _____

Lymph Nodes: _____

Throat Findings: _____

Other Pertinent Findings/Description: _____

_____

INFLUENZA ALGORITHM - To determine if influenza testing is appropriate.

ILI Present? Y / N

Cough: Y / N AND Fever: Y / N OR Body Aches: Y / N

Any Critical Values? Y / N Patient acceptance of test: Y / N

Documented Influenza Activity in Area: Y / N

TEST?? Y / N

Test Information: Rapid Flu A & B Results: A + / - B + / -

Lot: _____ Expiration Date: _____

Recommendations: _____

_____

FOLLOW-UP:

Date: _____ Pharmacist Initials: ____ Time: _____

Notes from follow-up call: _____

_____

Additional Follow-Up Needed? Y / N. If yes, when? _____

Appendix B

CLICK HERE FOR A WORD VERSION OF THE SAMPLE STREP TESTING PROTOCOL

SAMPLE STREP TESTING PROTOCOL

BACKGROUND AND PURPOSE

Group A Streptococcus is the bacteria that causes an infection in the throat and tonsils called strep throat. This can also lead to other serious diseases and cause hospitalizations, missed workdays, and more. Treatment for strep includes symptom management and antibiotics. Due to the possibility of the bacteria spreading to other parts of the body and causing more serious diseases, quick access to testing and diagnosis is critical. As a CLIA Waived facility, we can provide easy access to waived strep testing for those at low risk of complications from strep.

This document details the protocol staff will follow in each instance where we provide a strep test to a patient.

Training: [Name, Credentials] is certified by the [Name of Certifying Body] in Point of Care Testing for the Community Pharmacist. [Name, Credentials] will be responsible for the appropriate training of ____ Pharmacy staff. Training attestations are at the end of this protocol.

Tests: We will use a [Manufacturer, Name of Device] for Rapid Detection of Group A Strep (Lot: ____; expires: ____) and a [Manufacturer, Name of Device] (Lot: _____; expires: ____) to process all strep tests collected via this protocol. All manufacturer instructions will be followed in accordance with CLIA. Individual test lot and expiration numbers will be recorded on the patient intake form for quality assurance.

Patient Flow

Presentation: Upon initial presentation to the store, the patient will be greeted as is usual practice at _____ Pharmacy. If he or she asks specifically for a strep test, the patient will be directed to the closed-door counseling room, informed about the cost of the test and of the process for being tested, and instructed to start working on the patient intake and assessment form included at the end of this protocol.

If the closed-door counseling room is currently in use, the patient will be seated in the waiting area and provided the same information and patient intake and assessment form.

In the case where the patient does not directly ask for a strep test but a pharmacist or pharmacy team member recognizes the patient may benefit from a rapid strep test, the pharmacist will quickly explain the ability to provide a test in real-time, the cost of the test, and the process for being tested. If the patient is interested in the test they will be directed to the closed-door counseling room and asked to complete the patient information section of the intake and assessment form.

Data Entry: Upon completion of the form, a copy will be made and given to the data entry technician for entry into Rx30. Data entry may include a new patient profile if the patient is new to ____ Pharmacy or simply billing or the strep test.

The test will be billed with the patient's name, the pharmacist completing the test as the provider, the UPC number of the test (_____), origin code of ___, and a $___ cost not billed to any insurance or plan.

Patient Assessment: Upon completion of the patient information section of the intake and assessment form and delivery of the copy of the form to the data entry technician, the pharmacist or pharmacy intern will assess the patient, documenting assessment on the pharmacist section of the intake and assessment form.

This assessment will include:

- Blood pressure as measured by [name of device]
- Pulse as measured by [name of device]
- Respiratory rate
- Temperature as measured by [name of device]
- Oxygen saturation as measured by [name of device]
- Clinical presentation
- Review of symptoms documented by the patient
- Start date/time of symptoms
- Drug allergies documented by the patient
- Current medications documented by the patient

Following this assessment, the pharmacist (if assessment is completed by the pharmacy intern the intern will report out on the patient to the pharmacist at this point) will determine patient eligibility for testing based on the algorithm on the intake and assessment form. If the patient is eligible for a test, the pharmacist will complete the specimen collection and begin the test. The patient may opt to wait in the consultation room or roam the pharmacy as they desire while the test is being completed. Once the test is completed the pharmacist will document the test results on the assessment form and will discuss the results and next steps with the patient.

TEST RESULTS:

Positive Results: A positive strep test indicates a patient should receive antibiotic therapy. With the patient's permission and desire, a prescription will be obtained for said therapy using the algorithm at the end of this protocol.

If a patient is associated with a provider with whom _____ Pharmacy has a collaborative practice agreement, a prescription for the antibiotic therapy will be created by the pharmacist per this agreement. Prescriptions may also be created for prophylactic reasons per this agreement. Per these agreements, patient intake and assessment forms will be faxed to the provider in a timely fashion (by the end of the business day) for their records and review.

These prescriptions will be filled with the pharmacist as the prescriber, an origin code of ___, and billed to the patient's insurance as appropriate. The prescription of record will be written on a telephone prescription pad, signed by the pharmacist completing the test, and attached to a copy of the patient intake and assessment form before filing.

If the patient is not associated with a provider with whom ____ Pharmacy has a collaborative practice agreement, the pharmacist will call the office of the patient's primary care physician and request a prescription for an antibiotic medication based on the assessment and test results completed by the pharmacist. We will fax a copy of the patient intake and assessment form to the provider for their review and records.

If a prescription for antibiotic therapy is not immediately expected back from the provider, the pharmacy will offer to call the patient when the prescription is ready for pick-up or to deliver the prescription to the patient when it is ready.

If a patient presents outside of regular business hours for their prescriber or does not have a primary care provider, the patient will be encouraged to use an online tele-medicine service or take a copy of their intake and assessment form to a local urgent care center where a prescriber can prescribe antibiotic therapy.

Regardless of the antibiotic prescription availability and methodology, patients will also be counseled on products and recommendations for symptom management, infection control, and what to look for as signs of improvement and disease progression.

The testing algorithm should maximize positive predictive value of the testing but false positives are, of course, a possibility. The follow-up component of this program is designed to identify and treat false-positives.

Negative Results: A negative strep test most likely means the patient has a different, self-limiting viral infection that will likely resolve more quickly and with less severe risks than strep or it is a false negative.

Using this assumption and the algorithm that maximizes the negative predictive value of the test, recommendations will include symptom management with information for what to watch for regarding disease worsening or improving.

The gold standard that most doctor's offices have when there is a negative result is PCR. However, PCR will not be used, and the patient will have to take the next steps. The follow-up component of this program is designed to identify and treat false negatives. The results of negative tests will also be faxed to the patient's primary care provider for their review and records.

Completing the Transaction and Finishing Steps:

Following test result discussion, recommendations for OTC products, and provision of prescription medication (if applicable), the pharmacist will advise the patient to look forward to a follow-up call in 48 hours before sending them to the front register and home. Following the patient leaving the room, the room will be cleaned prior to the next patient entering the room.

Follow-Up: If not yet completed, the patient intake and assessment form will be faxed to the patient's primary care provider with a cover sheet explaining why the information is being sent.

The form will then be put in the dated trays near the data entry technician station for two days following the visit. Each morning, the data entry technician will give forms in that day's basket to the pharmacist for follow-up calls. These calls should be completed before noon and attempted at least twice.

The purpose of these follow-up calls is to assess the patient's condition and evaluate progression and/or need for referral to another care provider. Documentation of the follow-up call should be completed on the patient intake and assessment form.

If the patient is progressing well and does not require further follow-up, the completed intake and assessment form may be filed. If the pharmacist believes the patient would benefit from another follow-up call, the form should be returned to the dated bin for the appropriate day.

STAFF TRAINING ATTESTATION

I attest that I was trained on the delivery of point-of-care testing services in a community pharmacy satisfactorily, all of my questions were answered by [Pharmacist name] and I will comply with the contents of this protocol in the care of our patients.

Name	Date

PATIENT INTAKE AND ASSESSMENT FORM

[Pharmacy Name and Address] [Date Revised]

Patient Name: _____Gender: _____ DOB: _____

Patient Address: _____City/State/Zip: _____

Patient Phone Number: (____) _____-_____

Primary Care Physician: _____ Address: _____

Medication Allergies: _____

Current Medications: _____

_____

Past Medical History: _____

_____

Current Situation – When did your symptoms start? _____

Which of these do you currently have?

Fever: Y / N if yes, what temperature? _____

Headache: Y / N

Muscle Pain: Y / N

Sore Throat: Y / N

Runny Nose: Y / N

Cough: Y / N

Fatigue: Y / N

Head/Nasal Congestion: Y / N

Any other symptoms? _____

Have you taken any medications for these symptoms? Y / N

If yes, what and when? _____

Did you get a flu shot this year? Y / N

Are you a current smoker? Y / N

Any other recent medical concerns? Y / N

If yes, please describe: _____

_____

Pharmacy to Complete below this line.

Date: _____ Time Assessment Began: _____ Pharmacist Initials: _____

Referral Source: _____ Influenza Activity (if applicable): _____

First – Review patient information for completeness. Ask to fill in any gaps as needed.

Second – Look for any immediate 'rule outs.' If present, stop, explain, refer out for treatment.

Age: <15 or >80 years

Lung Cancer, Recent Pneumonia, Recent Hospitalization (< 30 days), Severe Lung Disease

If for sure no fever or complaint of feeling feverish, not strep or flu

Symptoms longer than 72 hours

Third – If you made it here, start clinical assessment.

CLINICAL ASSESSMENT

Blood Pressure: _____ /_____ If over 180/100, stop. Refer out for immediate treatment.

Pulse: ____ If over 100 bpm, stop. Refer out for immediate treatment.

Respiratory Rate/Description: _____

Temperature: _____ If more than 103° F (untreated), stop. Refer for immediate treatment.

Pulse Ox: _____ If under 90%, stop. Refer out for immediate treatment.

Tonsils: _____

Lymph Nodes: _____

Throat Findings: _____

Other Pertinent Findings/Description: _____

_____

STREP ALGORITHM - To determine if strep testing is appropriate.

Cough: Y / N Fever: Y / N Swollen Tonsils: Y / N Lymph Nodes Involved: Y / N

Age: 15-44 = 0, 45+ = -1

Centor Score: _____ (3 or 4 can be tested)

Any Critical Values? Y / N Patient acceptance of test: Y / N

TEST??: Y / N

Test Information: Rapid Group A Strep Results: Positive / Negative

Lot: _____ Expiration Date: _____

Recommendations: _____

_____

FOLLOW-UP:

Date: _____ Pharmacist Initials: _____ Time: _____

Notes from follow-up call: _____

_____

Additional Follow-Up Needed? Y / N. If yes, when? _____

TREATMENT ALGORITHM

Patients without Penicillin Allergy	Amoxicillin, oral 25 mg per kg twice daily x 10 days [≥20 kg (44 lb) = 500 mg]	
Patients with Penicillin Allergy	No Anaphylaxis	Cephalexin (Keflex), oral 20 mg per kg per dose twice daily x 10 days [≥25 kg (55 lb) = 500 mg per dose]
	Anaphylaxis	Clindamycin, oral 7 mg per kg per dose three times daily x 10 days [≥42.9 kg (94.3 lb) = 300 mg per dose]

Appendix C

POCT CASE STUDY: MT. CARMEL PHARMACY

Mt. Carmel Pharmacy co-owner and pharmacist Roger Paganelli provides a look into his innovative pharmacy-based POCT model that not only saved lives, but transformed healthcare delivery in an area where access is a barrier to receiving vital services.

TRANSFORMING COMMUNITY HEALTH WITH PHARMACY-BASED POINT-OF-CARE TESTING

In the wake of the COVID-19 pandemic, pharmacies across the United States found themselves at the forefront of a public health crisis. Among them, Mt. Carmel Pharmacy, located in the Bronx, New York, began redefining community health through Point-of-Care Testing (POCT) services, both in the pharmacy and in patients' homes.

GETTING STARTED

As a first step, Mt. Carmel Pharmacy named a medical lab director and applied for a Limited-Service Laboratory (LSL) License. The New York LSL License is the equivalent of the Federal CLIA waiver, and the medical lab director needed to be an MD, DO, or DDS in order to meet the LSL License requirements.

"Once we were granted the authority by the Federal government and the NY state government to do COVID testing, this opened the door for us to get a Limited-Service Laboratory (LSL) License."

TRAINING AND CROSS-TRAINING

Once Roger and the other pharmacists at Mt. Carmel received POCT training, they cross-trained their staff, producing additional team members capable of handling various aspects of POCT workflow. The staff members who were against being in close contact anyone with a communicable disease, were trained on other steps in the process, like communications and reporting.

"We interviewed our team to better understand strengths and weaknesses and then built in some flexibility to accommodate for schedules, time off, and common team dynamics. For those who enjoyed learning new skills, assigning them to new tasks on certain days of the week worked well because they had something different to look forward to."

UTILIZING TECHNOLOGY TO FREE UP TEAM MEMBERS

Technology plays a large role in streamlining POCT workflow at Mt. Carmel Pharmacy. Online scheduling software, like Acuity Scheduling allows for efficient patient management since most of the intake and follow-up steps, including collecting payment information and providing results, are handled without requiring

manpower from the pharmacy team. Mt. Carmel Pharmacy's investment in advanced technology, including text messaging software, resulted in a smooth and almost touchless POCT workflow, reducing patient contact during testing.

"The first part of the workflow is not getting the phones jammed up. We updated our phone IVR system to say "If you are calling for COVID vaccines or testing, Press 1. If you are calling for COVID testing, hang up and text the word "COVID" to [####], for vaccines, text the word "VACCINE" to [####]"

ENHANCING SAFETY WITH A WELLNESS CENTER

Mt. Carmel Pharmacy took proactive steps to enhance safety, especially with potentially contagious situations. They created a dedicated testing area, a Wellness Center, so that potentially contagious patients don't need to enter the pharmacy. Instead, patients approach a well-marked area, equipped with an intercom system and the pharmacy staff conducts appropriate testing while maintaining a safe distance. This approach prioritizes both patient safety and public health.

"Anyone who might have a communicable disease, we don't let them enter the wellness center. They tap on the window, or the door and they can talk to us through the microphone. There's a large sign that says, 'Get Tested Here.' There's an awning over the window in case it's raining or snowing. They open the window, we swab them, then they return to waiting area where the intercom is. That's our workflow for patients who are potentially contagious."

CONCIERGE TESTING

To improve their level of service, Mt. Carmel Pharmacy began offering concierge testing, home visits where they would be able to test entire families — sometimes 6 or more people at once. This approach not only improved accessibility but also opened doors to opportunities for at-home vaccine administration.

"In NY, you've got millions of people in a very small geographic area — super dense. With concierge testing, sick patients didn't have to get on a bus, get in an Uber, or walk to a hospital, so the response was just stellar — overwhelmingly positive."

EXPANDING SERVICES, STRENGTHENING VALUE

Initially, Mt. Carmel Pharmacy elected to only offer testing for COVID and blood glucose. Once the significant impact of their testing service was realized, they decided it was time to diversify. Next, they added testing for strep, A1C, influenza A/B, HIV, and cholesterol. By expanding their offerings, they set themselves even further apart from the competition.

"The expense for strep tests was minimal, so I added them to the list. They were only a couple dollars each test. Even if patients didn't pay via insurance, the cost was so low, I could just charge for the test directly."

COLLABORATION IS KEY

Throughout the COVID-19 pandemic and the implementation of POCT, Mt. Carmel Pharmacy worked closely with the Community Pharmacy Enhanced Services Network (CPESN USA), CPESN of New York, and other COVID work groups, sharing the latest COVID-19 updates, resources, workflow tips, and best practices.

"If I can't do it, I can't teach it, if I can't teach it, I can't scale it. As a CPESN luminary, I'm always looking to assist and empower the other pharmacists in my network. During the pandemic, we brought a tremendous amount of value to the community, the city, and the country. I was on scrum calls with leaders throughout the country and we were all sharing stories to learn more about what we were all doing."

FUTURE EXPANSION

Mt. Carmel Pharmacy is continually exploring opportunities to expand their POCT services. Soon, Roger would like to explore testing and treatment for sexually transmitted infections (STIs) and other diseases, particularly related to women's health. By doing so, they aim to provide a comprehensive solution for not only diagnostic testing, but immediate treatment for this patient population, significantly improving public health outcomes.

"It would be great if people with STI symptoms could go to one place to get all the care they need – the test, the results, and the treatment — all in one. This is part of the reason why STIs are so prevalent – non-diagnosis and therefore non-treatment. We also want to expand our services to help increase access to PrEP and PEP – we can test for HIV, and then we can start you on PrEP, if indicated, no need to make the process more complicated. The medical community needs to understand that pharmacy can do these things with our eyes closed!"

CONCLUSION

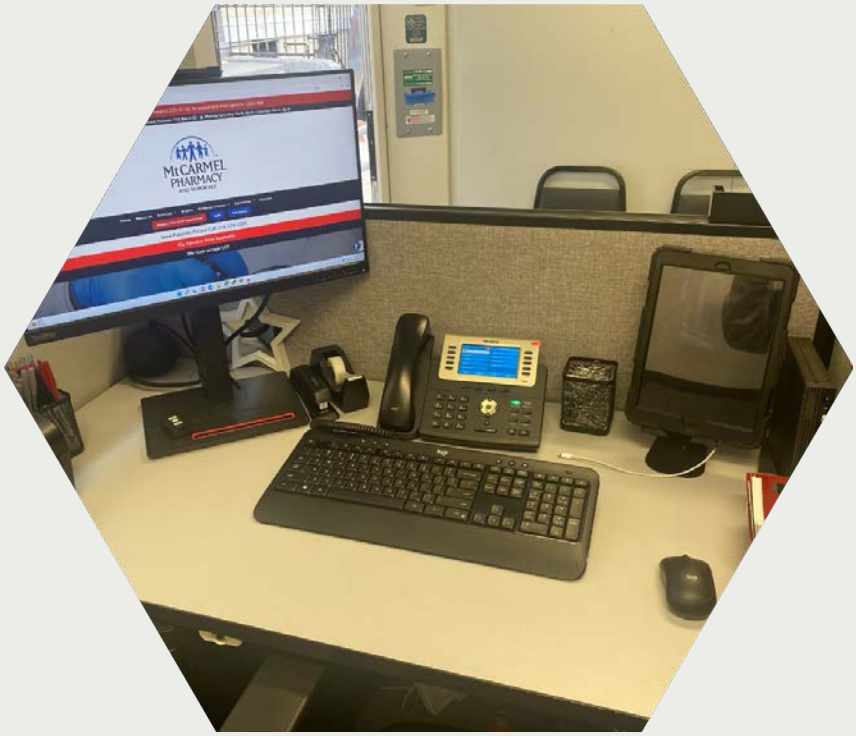
Mt. Carmel Pharmacy's journey from a traditional community pharmacy to a revolutionary healthcare hub is a testament to the transformative potential of pharmacy-based Point-of-Care Testing. By focusing on exceptional service, empowering staff, and leveraging technology, they have set new standards for community-based healthcare.

MT. CARMEL PHARMACY EXAMPLE PATIENT ENCOUNTER

A step-by-step example of a POCT encounter for Mr. Henry, a fictional patient at Mt. Carmel Pharmacy.

STEP 1: SCHEDULE AN APPOINTMENT

Mr. Henry schedules an appointment for a POC test via the pharmacy's website or mobile app, which integrates with Acuity Scheduling. During booking, he enters his personal information, insurance/payment details, and health history using a secure online portal, reducing the need for manual data entry at the pharmacy.



STEP 2: PHARMACY CHECK-IN

When Mr. Henry arrives, he reports to the Wellness Center, outside of the pharmacy to check-in and verify his identity. His pre-collected insurance and/or payment information is processed, and any copays or charges are communicated, streamlining the billing process.

Mt. Carmel Pharmacy emphasizes the importance of exceptional service over immediate profit. They are committed to providing an excellent customer experience, treating every patient with care and respect, regardless of payment method or insurance status.

STEP 3: PHARMACY MANAGEMENT SYSTEM

To organize the experience and ensure patient safety, the check-in technician processes the POCT test in Mr. Henry's profile in the pharmacy management system, similar to a prescription, and prints a 3-part prescription label with Mr. Henry's information to be placed on the results sheet, test card, and basket with supplies for his test.

STEP 4: SAMPLE COLLECTION AND TESTING

A pharmacy team member, certified in point-of-care testing, wearing appropriate personal protective equipment (PPE), approaches Mr. Henry through the Wellness Center window and swabs his throat to collect the specimen. The POC device analyzes the sample, and the test results are available within minutes.

STEP 5: RESULTS AND DOCUMENTATION

Mr. Henry's test results are recorded in his profile in the pharmacy management system. Simultaneously, he receives a text with a link to securely access his results online. Mr. Henry can immediately view or download his results conveniently from a smartphone or computer.

Mt. Carmel Pharmacy has a robust documentation system for POCT services to help with billing reconciliation, tracking results, and ensuring compliance with regulatory requirements.

STEP 6: REPORTING

To comply with public health reporting requirements, Mt. Carmel Pharmacy uses an automated process, integrated with their pharmacy management software, to securely transmit testing data for Mr. Henry and the other POCT encounters from that day to relevant local and state health authorities.

STEP 7: FEEDBACK AND REVIEW

After the testing experience, patients receive a survey link via text message, enabling them to provide feedback on their experience. This feedback loop is crucial for continuous improvement.

UPDATED FOR 2024!

NASPA Pharmacy-Based Point-of-Care Test & Treat

National Certificate Program

Point-of-care testing empowers clinicians to use effective, fast technology to aid their decision making at the "point-of-care" to improve patient health. Pharmacy-based point-of-care testing utilizes CLIA-waived tests that offer near immediate results. Pharmacists are increasingly offering this public health service to promote prevention, early detection, disease management, and treatment.

LEARN MORE

VISIT NASPA.US/POCT OR EMAIL EDUCATION@NASPA.US

Are you a Florida pharmacist? NASPA also administers the NASPA/FPA Pharmacy-based Point-of-Care Test & Treat Certificate Program.

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This test has not been FDA cleared or approved, but has been authorized by the FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless authorization is terminated or revoked sooner.

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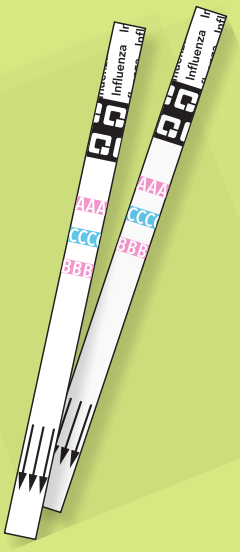
SARS Antigen*	Strep A	H. pylori
Influenza A+B	RSV	iFOB