

Overview of Point-of-Care Testing and the Role of the Pharmacist

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Key Points

- Stressors to the health care system, including physician shortages, an aging population, and a global pandemic, have expedited the expansion of the role of pharmacists in the health care team.
- Pharmacists are among the most accessible health care professionals in the community setting, as patients visit their community pharmacist about 12 times more frequently than they do their primary care provider.
- There is an opportunity to leverage pharmacists' expertise and unparalleled availability to combat the effects of physician shortages and provide increased access to health care.
- Few states include explicit legislation related to pharmacist's ability to provide point-of-care testing; however, policy interest in pharmacist prescribing has increased.
- Pharmacy-based point-of-care testing services reduce unnecessary antibiotic prescriptions, shorten time from symptom onset to the first dose of treatment, and improve patient satisfaction.

Introduction

Pharmacists have long been charged with the responsibility to use their knowledge and expertise to serve others. When a pharmacist takes the Oath of a Pharmacist, they vow to embrace changes that improve patient care, improve their own professional knowledge, and assure optimal outcomes for all patients.¹ The ways in which pharmacists adhere to this vow have changed greatly over time, but the underlying theme remains the same: to provide the highest quality of patient care to all of those in need.

Since the Oath of a Pharmacist was written, pharmacists' patient care services and pharmacy education efforts have expanded, and they will undoubtedly continue to do so. Stressors to the health care system, including physician shortages, an aging population, and a global pandemic, have helped expedite the expansion of the role of pharmacists in the health care team.^{2,3}

Pharmacists who were once viewed as an ancillary member of the team with only the

limited role of dispensing medications to their "customers" are now taking on more patient care responsibilities for their "patients" including immunizations, chronic disease management, and point-of-care testing (POCT) with prescriptive authority for minor non-chronic health conditions.⁴ State law governs a pharmacist's scope of practice and patient care services, and the extent of prescriptive authority varies state-to-state.^{5,6} Descriptions of various types of pharmacist prescriptive authority can be found in Table 1–1. More information about the requirements of protocols is available in Chapter 3. Nevertheless, the general trend continues to be toward increasing patient's access to care by allowing pharmacists to assume more responsibilities as part of an interprofessional health care effort. The focus of this chapter is to identify opportunities to use POCT to test and treat minor health conditions under an established protocol in the pharmacy setting while highlighting the positive impact of POCT on patient care and satisfaction.

Table 1–1. Prescriptive authority definitions

Term	Definition
Collaborative practice agreement (CPA)	Pharmacist prescriptive authority strategy in which pharmacists can initiate and modify selected prescription medications for both chronic and non-chronic conditions, as outlined in a protocol, under the supervision of a physician who also cares for the patient (e.g., collaborative hypertension management). ^{3,15} The CPA may be patient-specific, population-specific, or medication-specific. ^{5,6}
Government protocol	Pharmacist prescriptive authority strategy in which pharmacists can prescribe a medication for patients following a protocol that specifies pharmacist training, specified patient inclusion and exclusion criteria, and specific medications, in a non-patient-specific protocol (e.g., statewide protocol for naloxone). ^{3,15} Protocols may be local, state, or federal. ⁵
Standard-of-care prescribing	This type of prescribing is similar to physician prescribing. Pharmacists use their own professional judgment to prescribe medications within a standard of care, that is, what other prudent pharmacists would do in the same or similar situation. ⁵ For pharmacists, prescribing may require or not require a diagnosis. ⁵
Dependent prescribing	Pharmacist prescribing pursuant to a collaborative practice agreement. ⁵
Independent prescribing	Pharmacists independently prescribe certain drugs in certain circumstances, either through a government protocol or through standard-of-care prescribing. ⁵

Evolution of Point-of-Care Technology

POCT is diagnostic testing that takes place near the patient’s site of care outside of a clinical laboratory with the use of a portable device.^{4,7} These tests obtain rapid and real-time results to allow caregivers to make patient care decisions within minutes. POCT has been used for years to monitor chronic disease states in a doctor’s office (cholesterol panels, glycated hemoglobin, and international normalized ratio [INR]), as well as to monitor acute conditions at the patient’s bedside, including electrolyte abnormalities and infectious diseases.⁷ Pharmacists have used POCT for decades to screen patients for disease and monitor drug therapy by conducting testing similar to that used in physician practices.^{8,9} POCT also provides opportunities for rapid diagnostic testing to quickly diagnose infectious diseases. POCT tests fall under the Clinical Laboratory Improvements Amendments 1988 (CLIA) and most are considered waived tests.¹⁰ The types of test categories are waived, moderately complex, and highly complex; waived tests are simple to conduct, with minimal risk of error, whereas moderately complex and

highly complex tests require more training or testing experience and more frequent quality control.¹¹ As POCT technology advanced, testing devices became easier to use and more portable, allowing for POCT to be used by individuals with minimal training in various practice sites, including pharmacies and patient’s homes.⁷

Test-and-treat initiatives take the concept of POCT further by providing treatment recommendations in real-time based on the results of testing to screen and diagnose patients at increased risk for a particular condition.¹² Historically, test-and-treat initiatives have been population-based strategies.¹² Pharmacists have adopted the test-and-treat term to refer to the use of POCT (testing) and prescription of treatment (treat) as a result of patient presentation and testing. At the legislative level, the use of test-and-treat language expands the responsibility for diagnosis and prescribing treatments from physicians to include other health professions, thus modernizing the scope of pharmacist practice; however, this shift has been controversial. Table 1–2 summarizes definitions related to this topic. Pharmacists’ authority to provide test-and-treat services, protocol requirements, and disease states

Table 1–2. Testing definitions

Term	Definition
Point-of-care testing (POCT)	Diagnostic testing that takes place near the patient’s site of care outside of a clinical laboratory with the use of a CLIA-waived device. ^{4,5}
Rapid diagnostic test (RDT)	Group of tests designed to detect pathogen-specific antigens, nucleic acid sequences, or host antibody responses to certain pathogens with short performance times, and may be performed under a certificate of waiver. ⁴⁰
Test-and-treat (TNT)	Intervention strategy in which a population is screened for a disease state/condition using POCT and treatment is prescribed for eligible patients based on test results. ¹²
Clinical Laboratory Improvement Amendments of 1988 (CLIA)	Regulations are comprised of federal standards that apply to all U.S. facilities that test specimens collected from a human being for health assessment or to diagnose, prevent, or treat humans. ^{10,11}

covered as part of these services vary by state. However, the use of test-and-treat specifically in the pharmacy setting to detect, triage, and provide treatment for various acute conditions such as influenza or streptococcal pharyngitis has gained traction as pharmacies have become a destination for patients to seek medical advice, unloading some of the strain on urgent care settings and emergency departments.² In March 2022, the Biden-Harris Administration introduced a nationwide Test to Treat initiative to increase access to affordable COVID-19 treatment, allowing pharmacists to conduct POCT services for COVID-19 and prescribe treatment to those who meet certain requirements regardless of current state legislation, which increased awareness and public perception.¹³

Overview of the Health System and Pharmacists' Unique Position

National organizations such as the Centers for Disease Control and Prevention (CDC) and the U.S. Department of Health and Human Services (HHS) have envisioned the need for health care reform to improve access to care and reduce health disparities.^{14,15} The focus on increasing access to care is in part due to both current and projected physician shortages, as well as the strain on the health care system due to COVID-19.^{2,16} The Association of American Medical Colleges (AAMC) reports a projected total physician shortage of between 37,800 and 124,000 physicians by the year 2034.¹⁷ The workforce shortage problems are especially apparent in the primary care setting and in rural areas. The patient-to-primary care physician ratio in rural areas is 39.8 physicians per 100,000 people, while the ratio in urban areas is 53.5 physicians per 100,000 people.¹⁸ These shortages reveal a workload that is not sustainable as the population continues to age and highlight the importance of using a

team of health care providers, including pharmacists, to provide quality patient care.³

Because pharmacists are often recognized as one of the most accessible health care professionals in community-based settings, there is an opportunity to leverage pharmacists' expertise and unparalleled availability to combat the effects of physician shortages and provide increased access to health care. Pharmacies are located throughout the community and often can be reached while grocery shopping or via a drive-thru, as well as after work and on weekends. About 90% of Americans live within 5 miles of a pharmacy, and patients visit their community pharmacist about 12 times more frequently than they do their primary care provider.^{19,20} Therefore, pharmacists are uniquely positioned to offer testing and treatment to communities using POCT and prescriptive authority, eliminating access as a barrier to receiving care.¹⁶

Current Landscape

The lack of access to quality and timely health care often leaves patients with limited choices when facing an acute health condition. By providing POCT to triage these minor conditions, pharmacists create a more resilient health care system and provide additional options for patients to receive necessary care at convenient locations in community-based settings.¹⁶ Allowing pharmacists to prescribe treatments based on the results of POCT via test-and-treat strategies leads to earlier access to care and treatment for patients, which can be lifesaving. Pharmacists can initiate and modify selected prescription medications via dependent prescribing, as well as by collaborative prescribing as established by a collaborative practice agreement (CPA).^{3,5} However, these services are not currently offered at every pharmacy and the extent of prescriptive authority varies widely. As

alluded to previously, this variation can be explained by the fact that the scope of pharmacy practice is regulated at the state level in the United States.²¹

Independent prescribing allows a pharmacist to prescribe medications for patients that meet specified criteria, and the formulary and amount of medications that can be prescribed are generally limited in comparison with those of physicians.^{3,5,21} Two examples of independent prescribing in statewide protocols are birth control medications and naloxone.²¹ Dependent and independent prescribing can be used for both chronic and non-chronic conditions, allowing a pharmacist to initiate, modify, or discontinue prescription medications under their state-determined scope of practice or a written agreement or protocol with a supervising physician.^{3,5,21} Dependent prescribing under a CPA typically only occurs for patients collaboratively managed by a pharmacist and physician, whereas independent prescribing can be done for any patient in a given state if they meet the outlined requirements of that state.²¹ While there are advantages and disadvantages to each prescriptive authority model, the general trend has been toward more legislation specifically allowing pharmacy-based POCT. At this time, few states include explicit legislation related to the ability of pharmacists to provide POCT; however, policy interest in pharmacist prescribing has started to increase.^{21,22}

The first steps toward pharmacist prescribing occurred in 1979 in Washington State, when its Pharmacy Practice Act was amended to authorize pharmacists to broadly initiate and modify drug therapy. Although not specific to non-chronic conditions in the setting of POCT, this amendment allowed pharmacists in Washington to provide expanded pharmacy services such as management of medications for asthma and diabetes.²³ To further support pharmacists, Washington also passed state legislation to

give pharmacists provider status and allow them to bill for their clinical services.²³ Washington's progressive pursuit of provider status and expanded pharmacy services paved the way for other states. As of the end of 2023, more than 20 states allowed prescribing authority for pharmacists to treat specific health conditions that can be detected via a CLIA-waived diagnostic test under a statewide protocol or as part of a CPA with a supervising physician.²² Each state varies with regard to the disease states that can be treated; however, the most commonly included disease states tend to require minimal treatment, including influenza, streptococcal pharyngitis, and urinary tract infections (UTIs).²² Among states that allow test-and-treat services in the pharmacy setting, the prerequisites for pharmacists wishing to offer these services vary widely; important state-to-state differences are highlighted below.

Kentucky legislation allows pharmacists to use board-approved and physician-signed protocols to test and treat for influenza, streptococcal pharyngitis, UTIs, and other self-limiting non-chronic conditions.^{22,24} Prior to providing these services, the protocols specify that pharmacists must receive education and training from a provider accredited by the Accreditation Council for Pharmacy Education (ACPE) or approved by the Kentucky Board of Pharmacy. The protocols also contain information regarding inclusion criteria, exclusion criteria, medications that can be prescribed by a pharmacist, and procedures related to follow-up, monitoring, documentation, and physician notification.²⁴

In February 2022, Florida passed legislation to allow pharmacists to test and treat patients for minor, non-chronic health conditions that are generally managed with minimal treatment or self-care, including, but not limited to, influenza and streptococcal infections.²⁵ In order to provide these services, a Florida pharmacist must add a Pharmacist

Test and Treat Certification to their license and complete a 20-hour Florida Board of Pharmacy-approved certification course.²⁶ Florida also requires pharmacists to enter into a written protocol with a supervising physician outlining the specific categories of patients the pharmacist may treat, physician instructions for patient assessment and treatment for the pharmacist to follow, and a schedule and process for the pharmacist to notify the physician of the treatment plan for each patient.^{25,26} These are just two examples of significant advancements on the state level to improve access to care; however, several opportunities exist for further policy breakthroughs.³ Montana and Idaho have expanded pharmacists' scope of practice related to independent prescribing under a standard-of-care prescribing model, under which pharmacists are granted broad authority to administer, interpret, and act on test results if they have the necessary clinical ability.⁵ Montana's model is non-diagnostic, while Idaho has included prescribing within the pharmacist's scope of practice.⁵

Impact of Pharmacy-Based Point-of-Care Testing

The impact of pharmacy-based test-and-treat services has been studied in several countries, including the United Kingdom, Canada, New Zealand, and the United States.^{27,28} Aside from the convenience, these services have been shown to reduce unnecessary antibiotic prescriptions, shorten the time from symptom onset to the first dose of treatment, and improve patient satisfaction. In Canada, the RxOUTMAP study analyzing pharmacist-led POCT for UTIs reported that a majority of the participants expressed a high level of trust in their pharmacist, appreciated the accessibility of the pharmacist, and were ultimately very satisfied with their visit.²⁹

Acute pharyngitis is generally self-limiting and can be caused by a variety of bacteria and viruses, with viral infection being more common.³⁰ About 70–95% of pharyngitis cases are caused by viruses, yet about 60% of patients are prescribed antibiotics after presenting with a sore throat.^{30,31} Pharmacy-based POCT for *Streptococcus* presents an opportunity to promote prompt access to antibiotic therapy for patients, while preventing severe complications and avoiding unnecessary treatment of patients with viral pharyngitis.³¹ An observational study that retrospectively analyzed 204 pharmacy locations in Canada providing POCT for streptococcal pharyngitis found that 68.7% of those who tested positive received an antibiotic prescription within the same day, while only 5.6% of those who tested negative received a same-day antibiotic prescription. A few of the pharmacy locations did not have prescriptive authority, so the antibiotics prescribed to those who tested negative resulted from medical referral. Patients who participated in pharmacy-based POCT were surveyed, and 81% of participants reported that they were either very satisfied or satisfied with the service, while 93% of respondents reported that they would be very likely or somewhat likely to use the service in the future. The most common reasons cited for wanting to use the service again were efficient service (54%) and quick results (26%).³¹

Another disease state with boundless potential for pharmacist impact is influenza. Antiviral treatment for influenza is most effective when taken within 48 hours of symptom onset, making access to timely care of the utmost importance.³² A multicenter study of 13 pharmacies in four states throughout the United States randomized 27 patients and compared the efficiency of POCT services when pharmacists could prescribe oseltamivir as part of a pre-arranged physician-approved CPA (treatment group) versus POCT

services when pharmacists could conduct the testing and had no prescriptive authority, so that patients with a positive result had to be referred to their primary care provider for treatment (referral group). For those who were prescribed oseltamivir, the mean time to the first dose was significantly reduced from 385.3 minutes in the referral group to 57.8 minutes in the treatment group.³³ Although the sample size was small, this study shows that POCT paired with prescriptive authority can shorten the time to treatment for diseases with public health importance such as influenza.

Opportunities in Pharmacy-Based Point-of-Care Testing

POCT and test-and-treat services in a pharmacy setting are not just convenient options for patients; for some patients, they are the only option. Findings from a multicenter study analyzing 55 community pharmacies offering POCT for streptococcal pharyngitis from October 2013 to August 2014 revealed that only a little over 50% of the patients had a primary care provider and more than 40% of the study population accessed the POCT services during evening hours, on the weekends, and on holidays.³⁴ Furthermore, in 2017, the average wait time between a patient calling a doctor's office and seeing a physician to complete a routine physical was 24 days for a new patient visit and 29 days for an established patient.³ Therefore, while access to health care services is a major concern, timely access is just as important in ensuring the detection and treatment of non-chronic conditions in patients with limited access to health care providers. Allowing pharmacists to test for these conditions utilizing a test-and-treat strategy can alleviate some of the burden on urgent care centers, emergency departments, and primary care offices to ultimately improve patient outcomes.

In order to provide POCT services, pharmacies must enroll as a CLIA-waived testing location through the Centers for Medicare and Medicaid Services (CMS).² The procedures for enrollment include completing the appropriate form, paying biennial fees, and complying with the manufacturer-recommended policies and procedures for each testing device to ensure safe and accurate POCT.⁷ As of 2020, approximately 15,671 pharmacy locations were registered as a CLIA-waived testing site, which represents a significant increase from 10,626 CLIA-waived pharmacy testing sites in 2015.³⁵ It is likely that there are several reasons for this 45% increase in testing sites over a 5-year period, but this change was mainly driven by COVID-19 testing efforts in the pharmacy setting. In addition, the percentage of pharmacies with a CLIA waiver varies significantly by state, with the lowest prevalence (2.92% of pharmacies) in Pennsylvania and the greatest prevalence (56.52% of pharmacies) in Washington.³⁵

In addition to the regulatory barriers to implementing pharmacy-based POCT and test-and-treat services, logistical barriers to implementing these services have been addressed in the literature. To demystify the myth that POCT would not be feasible to incorporate into the community pharmacy setting, a time-and-motion study examining three community-based pharmacy locations offering influenza rapid diagnostic testing (RDT) found that the average time to complete a patient encounter, including testing, was 35.5 minutes ($\pm$ 3.1 minutes), while the average pharmacist participation time per encounter was 9.4 minutes ($\pm$ 3 minutes). From the patient's perspective, the total average wait time was 20.6 minutes, most of which was due to the time waiting for the RDT result.³⁶

Recent national efforts to detect, treat, and prevent human immunodeficiency virus (HIV) in order to dampen its spread created

an opportunity for pharmacists to implement HIV POCT services in the pharmacy setting. In 2021, there were more than 1.2 million people living with HIV in the United States, and 13% of those people were unaware of their infection and therefore unlikely to prevent transmission of the disease or obtain appropriate treatment.³⁷ In the setting of HIV, pharmacies provide a non-stigmatizing and accepting setting that is conducive to providing HIV prevention and treatment strategies in real-time for those at risk.³⁸ A study conducted in a single independent community pharmacy in Washington analyzed the value of pharmacy-based HIV POCT provided to 50 participants. They found that although POCT only detected 1 HIV patient

who tested positive, the pharmacist's assessment led to 76% of the study population (n = 38) qualifying for and receiving pre-exposure prophylaxis (PrEP) therapy.³⁹ Pharmacist referrals to an alternative health care provider were made for 28 participants, and 71% of those referred established care with a health care provider following their interaction at the pharmacy.³⁹ Whether they are initiating antiretroviral therapy or recommending postexposure and preexposure prophylaxis (PEP and PrEP), pharmacists have opportunities to help end the HIV epidemic by providing care to patients who may not have been able to be screened otherwise and linking patients to appropriate health care providers.

Conclusion

From the advent of Medication Therapy Management services and immunization authority to collaborative practice and test-and-treat strategies using POCT, the focus of pharmacists continues to shift from the drug product to the patient. This shift was tested during the coronavirus pandemic, when the HHS authorized all pharmacists to provide COVID-19 testing regardless of state law in order to increase access to care in a time of urgent need.^{13,20} The COVID-19 pandemic reaffirmed the importance of pharmacists practicing at the highest level of their license and the need to expand their clinical role to include the ability to test and screen for various minor health conditions. Pharmacists with prescriptive authority to provide treatment for those with a positive result, as well as symptom management and education for those with a negative result was instrumental during the pandemic. In addition, patients continue to report the convenience of quality care as an important factor for determining their preferred site of care.⁴¹ Pharmacists are uniquely positioned to serve as an alternative avenue for patients to receive quality care in a timely manner.

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