Point-of-Care Testing  
*Background Paper Prepared for the 2015–2016 APhA Policy Committee*  
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**Issue**

The APhA Board of Trustees has directed the 2015–2016 Policy Committee to recommend policy to the APhA House of Delegates related to pharmacists’ involvement in point-of-care testing (POCT), including rapid diagnostic testing.

**Summary of Key Concepts**

- The pharmacy profession is working diligently to develop a sound, structured plan that will provide medication therapy management, chronic condition management, and other health and wellness services within contemporary health care. As health care continues to shift toward primary and preventive care, performing POCT may become a standard area of practice for all pharmacists.
- Pharmacists are permitted under federal law to perform POCT by using tests that have been waived by the Clinical Laboratory Improvement Amendments (CLIA).
- However, pharmacists’ state-level scope of practice affects whether and how they can perform these tests at the state level; therefore, testing is inconsistently applied.
- Further education and training are needed to support pharmacist and student pharmacist participation in POCT programs.
- Pharmacist and student pharmacist participation in POCT programs could be an important component in expanding team-based models of care, improving patient access to needed services, and supporting the role of the pharmacist as a provider of patient care.
- The role of POCT in supporting the pharmacists’ role on the health care team needs to be identified. Moreover, protocols, policies, procedures, and tools supporting consistency and continuity of care provision should be developed.
- The following potential barriers could affect pharmacist and student pharmacist participation in POCT programs: (a) lack of payment and coding mechanisms, (b) lack of standardized training and education across the profession, (c) lack of standardized documentation systems and follow-up procedures, (d) inconsistency in providing POCT services, (e) and perceived pushback from medical and other related health professionals.

**Introduction**

The pharmacy profession is at a crossroads. Efforts to expand the patient care activities of pharmacists to include areas of primary, preventive, and chronic care, while at the same time improving access, quality, and cost effectiveness of such care, have aligned with the profession’s pursuit of recognition as health care providers under federal and state law. One such area of expanding patient care activities is the involvement of pharmacists and student pharmacists in POCT programs.

According to the Centers for Disease Control and Prevention (CDC), an estimated 7 million people have undiagnosed diabetes, 240,000 people have undiagnosed human immunodeficiency virus (HIV), and 800,000 people have undiagnosed hepatitis C. All of those diseases are detectable by POCT, including rapid diagnostic testing (RDT) programs, and the early detection of these conditions can lead to better patient outcomes.
POCT programs can also contribute to the successful monitoring and management of various chronic diseases, thus helping address the increasing burden of chronic disease. With more than 60,000 community pharmacies in the United States, and an estimated 4,000 weekly patient visits per pharmacy, pharmacists undoubtedly have the access necessary to make a positive effect on the health and well-being of patients in various areas of patient care.²

Although some aspects of POCT programs have been standard practice in health care for a number of years, the participation of pharmacists in such programs has risen somewhat slowly in the past 10–15 years as pharmacists have become increasingly involved in direct patient care activities, disease-monitoring programs, and patient self-monitoring initiatives.²

A number of factors may have contributed to this relative lack of POCT program expansion, including, but not limited to, the following:²

- Pharmacists’ lack of familiarity with POCT program processes
- Pharmacists’ lack of physical assessment and specimen collection skills
- Low level of acceptance of pharmacists’ by other health care providers
- Administrative burden of meeting state regulations, federal requirements, and other third-party demands
- Feasibility of incorporating POCT programs into the pharmacy workflow
- Financial considerations regarding testing equipment, supplies, and documentation programs
- Relatively limited financial incentives to provide such testing

In the past 10—15 years, a number of research projects have been implemented to demonstrate the positive effect that pharmacist-provided care services can have in the management of various disease states. One such venture, Project ImPACT: Hyperlipidemia, was a community pharmacy–based demonstration project that incorporated pharmacists to provide POCT. In that project, which was supported by the APhA Foundation, pharmacists in 26 community pharmacies and clinics used Cholestech LDX Analyzer devices to measure the achievement of National Cholesterol Education Program (NCEP) target lipid goals in 397 patients over approximately 2 years. At the end of that groundbreaking program, 90.1% of participants were observed to be compliant with medication therapy, and 62.5% of participants reached and maintained their NCEP target lipid goal at the end of the observation period.³

The burden of chronic disease is growing along with the aging of the population and the increasing complexity of the health care system. Pharmacists are in the perfect position to contribute to the care of patients through participation and leadership of POCT programs.

Because the terms point-of-care testing and rapid diagnostic testing are sometimes used interchangeably, the following general definition will be used within this discussion paper: POCT “involves performing a robust diagnostic test outside of a laboratory at or near the patient that provides a reliable result rapidly to aid in disease screening, diagnosis, and/or patient monitoring.”⁴ Examples of POCT include, but are not limited to, obtaining a serum creatinine level to gauge renal function; ordering a hemoglobin A1C level to determine blood glucose control; and performing RDT for the confirmation of a specific disease (e.g., testing for Group A Streptococcus, influenza, respiratory syncytial virus, hepatitis C, HIV).²

Legislative and Regulatory Considerations

Federal law does not specifically preclude pharmacist or student pharmacist participation in POCT. However, a number of state legislative and regulatory considerations should be considered with respect to participating in these services.
**CLIA-Waived Tests**

To ensure the accuracy, quality, and reliability of laboratory test results, the Clinical Laboratory Improvement Amendments were passed in 1988 and finalized in 1992. CLIA requires laboratories to meet standardized certification parameters in order to perform tests on human specimens. However, if a laboratory test could be performed with a “minimal level of complexity and low risk of erroneous results,” an exception could be granted to perform this testing in a nonlaboratory setting (e.g., pharmacy, clinic, or other nonlaboratory setting). Those excepted tests are known as **CLIA-waived tests**.

Therefore, before initiating POCT services, pharmacies must obtain a CLIA Certificate of Waiver through their state office of the Centers for Medicare and Medicaid Services (CMS). Of note, in 2012–2013, only 14% of the approximately 60,000 community pharmacies in the United States were providing CLIA-waived POCT services.

Of the 120 CLIA-waived laboratory tests available in the United States, a smaller number are generally considered appropriate for inclusion in most pharmacy-based POCT programs. Some of the POCT services that may be conducted in pharmacies include the following:

- Cholesterol
- **Group A Streptococcus** (RDT)
- **Helicobacter pylori** (RDT)
- Hemoglobin A1C
- Influenza (RDT)
- International normalized ratio (INR)
- Serum chemistries (e.g., sodium, potassium, chloride)


**State Regulations**

A major barrier to the widespread expansion and growth of pharmacist-led POCT programs is the variability and limitations of state legislation and regulation with regard to these initiatives. According to Gubbins et al., “if the practice act of a state does not explicitly address POC testing directly, such tests may be addressed under collaborative drug therapy management (CDTM) provisions in state regulations or statutes.” As of 2012, 44 states had a provision in their state pharmacy practice acts to allow for CDTM. Of those 44 states, only 19 (Arkansas, California, Colorado, Georgia, Idaho, Iowa, Louisiana, Maryland, Michigan, Montana, New Jersey, Nebraska, New Mexico, North Dakota, Oregon, Texas, Vermont, Washington, and Wyoming) had specific language in their CDTM provisions allowing for pharmacist participation in POCT programs. Of those 19 states, only 7 (California, Colorado, Georgia, New Jersey, North Dakota, Pennsylvania, and Washington) also had POCT-related provisions in their state pharmacy practice acts (outside of CDTM language).

In a separate review by Gubbins et al., he found that eight states explicitly included POCT-related language in their respective pharmacy practice acts. In five of these states, the respective practice acts outlined specific POCT programs in which pharmacists are allowed to participate.

Because conducting testing without a plan for follow-up or treatment is generally counterproductive, practitioners interested in offering POCT programs should become familiar with their state laws and regulations related to the provision of POCT. If applicable, they should also learn about participation in CDTM, collaborative practice agreements, initiation of standing orders, or implementation of treatment protocols. Although these areas are not inherently necessary in the provision of POCT programs, their inclusion can likely facilitate the effectiveness and efficiency of POCT programs.
Other Regulations

Because POCT programs can potentially increase pharmacist and student pharmacist exposure to bloodborne pathogens and other hazards, practitioners should also review regulations from the Occupational Safety and Health Administration (OSHA). OSHA regulations include language related to the use of appropriate personal protective equipment and the provision of adequate training, documentation, and emergency plans.5

Education and Training

According to Burley et al., more than 85% of pharmacists and student pharmacists who participated in a recent survey responded that they did not about CLIA-waived tests in school and “would not be comfortable discussing tests or test results with their patients or prescribers.” Further, a survey conducted by the Society of Infectious Diseases Pharmacists indicated that more than 66% of colleges of pharmacy did not include RDT-related information in their curricula.2

As with any evolving or expanding area of patient care, concerns arise about the availability of standardized, appropriate training in the development and implementation of pharmacist-provided POCT programs. Many schools and colleges of pharmacy have included aspects related to POCT in their curricula over the years. However, in its Guidance for Standards 2016, the Accreditation Council for Pharmacy Education (ACPE) included information encouraging schools and colleges of pharmacy to ensure graduates are competent to “collect, interpret, and make recommendations based on the results of health and wellness screenings and diagnostic tests.”7 As a result of that recommendation to PharmD programs across the country, the expansion of POCT activities is expected to continue.

To assist in educating and training those practitioners already in the work force, individual national and state pharmacy associations have provided continuing education programs related to laboratory and POCT services. A number of state Boards of Pharmacy require related continuing education before participation in POCT and laboratory testing programs. For example, the Florida Board of Pharmacy requires pharmacists (consultant pharmacists and pharmacists holding the Doctor of Pharmacy degree) who wish to order and evaluate laboratory tests in long-term care or home health settings to complete at least a 3-hour initial certification course and at least a 1-hour recertification course.8

In addition, the National Association of Chain Drug Stores (NACDS) recently partnered with clinicians from Ferris State University College of Pharmacy, University of Nebraska Medical Center College of Pharmacy, and Michigan Pharmacists Association to offer a 20-hour certificate training course related to POCT. The Community Pharmacy–Based Point-of-Care Testing Certificate Course provides community pharmacists, academicians, and other interested practitioners with the skills necessary to develop and implement a collaborative testing program for influenza, Group A Streptococcus, HIV, and hepatitis C. A Train-the-Trainer Program has also been developed to assist in expansion of the POCT and RDT initiatives across the country. For more information about this certificate program, visit http://www.michiganpharmacists.org/resources/pointofcare.9

Documentation and Follow-up

Although pharmacist-provided POCT can afford additional opportunities to affect patient health and well-being, interested practitioners should carefully consider how testing results should be documented and shared with other health care providers. Use of standardized forms and documentation procedures, such as subjective (data), objective (data), assessment, plan (SOAP) notes or other recordkeeping processes, can contribute to a patient’s continuity of care, provide legal evidence of the test(s) conducted and results obtained, and potentially provide proof of testing for billing purposes.5 Providers should use the
communications and documentation systems available to them. Although the electronic documentation of POCT data and exchange of information among providers is the preferred means of communication for these activities, the infrastructure to support the direct exchange of health information is still evolving. This direct interface will improve continuity of care and allow the physician and other health care providers to monitor the patient more effectively and efficiently.

At the same time that documentation and follow-up systems are being evaluated, special consideration should also be given to the potential connectivity of POCT devices used during patient testing. Many biotechnology companies have developed multiple-use POCT devices capable of administering multiple tests with one sample. Such devices may also be able to download patient testing results to individual electronic health records and testing site databases.

Payment and Coverage

As with other CLIA-waived tests, pharmacists providing POCT services can charge patients directly or potentially bill third-party payers (as long as the third-party payer is willing to pay for the test and state practice laws, regulations, and other documentation requirements are met). Although this ability to bill third-party payers is available—on a limited basis—the expansion of POCT programs has remained relatively low, especially in view of the length of time CLIA-waived tests have existed and the comparative ease of use in providing such tests.

From 2011 to 2013, Darin et al. evaluated the acceptability and feasibility of providing RDT for patients with HIV in two independent community pharmacies. Of the 69 participants screened, 37 were covered by third-party insurance, 13 were covered by Medicaid, 3 were covered by Medicare, and 14 had no insurance coverage. Within this group, 19 participants indicated they would be willing to pay for the HIV test, and 44 participants responded they might pay for the HIV test, depending on the cost. Approximately 80% of participants indicated they would be willing to pay $16–$20 or less for the HIV test, and 9% of participants stated they would pay $30 or more. From the results of this study, one can infer that payment and coverage considerations are a major factor in patient acceptance of such testing, regardless of the perceived potential severity of the disease for which the patient is being tested. Further, as education and training programs are expanded across the country, professional stakeholders should continue outreach to policy makers, third-party plans, and other interested groups to ensure that pharmacist-provided POCT programs are included in future payment and coverage discussions.

Quality Improvement Initiatives

Recent changes to health care laws have included a greater focus on health care spending that improves patient outcomes and a greater scrutiny in spending that does not. A major effort to improve patient outcomes, while addressing fiscal responsibility, is the development of various quality improvement initiatives in all areas of the health care system. Although efforts to address health care quality have been made in various accreditation and process improvement programs over the years, specific programs and measures are now in place to address the improvement of patient outcomes by targeting pharmacy-related areas in health plans, Medicare, and Medicaid. Pharmacists can use POCT to help them track and aid patient progress toward meeting established therapeutic goals.

**Pharmacy Quality Alliance Performance Measures**

The Pharmacy Quality Alliance (PQA) has developed performance measures that are specific quality-related metrics applicable to POCT tools to assist pharmacists in monitoring and influencing patient care progress:

- Proportion of Days Covered (PDC)
- Adherence to Non-Warfarin Oral Anticoagulants
Medicare Star Rating System

Pharmacists’ use of POCT in providing patient care services can assist them in helping patients achieve health outcomes, and ultimately contribute to quality measures. CMS uses a five-star quality rating system to measure Medicare beneficiaries’ experience with their health plans and the overall health care system. This rating system applies to all Medicare Advantage (MA) plans: health maintenance organizations (HMOs), preferred provider organizations (PPOs), private fee-for-service (PFFS) plans, and prescription drug plans (PDPs). Because star ratings can affect plan revenue, reimbursements, and enrollment, the inclusion of pharmacy- and medication-related measures presents an opportunity for pharmacists to contribute directly to the rating of plans and the overall care received by patients.

Medicare Part D Star Ratings are based on measures of a health plan’s rating across the following five domains:

1. Helping plan members stay healthy
2. Managing chronic conditions
3. Members’ experience with their health plan (i.e., plan responsiveness, care, and quality)
4. Members’ complaints or problems getting services, and improvement in performance
5. Health plan’s customer service

In addition, Medicare Part C drug plans are rated on the following domains:

1. Drug plan customer service
2. Members’ complaints or problems getting services, and improvement in performance
3. Members’ experience with the drug plan (i.e., plan responsiveness, care, and quality)
4. Patient safety and accuracy of drug pricing

Although the star rating system domains do not specifically mention the role of pharmacists, the effect of pharmacists in “managing chronic conditions” through medication management activities is undeniable. Further, by becoming more involved in POCT programs, pharmacists can assist health plans in meeting their star measures by playing a larger role in “helping plan members stay healthy,” through providing vaccines, contributing to infectious disease testing surveillance, and offering various screening services. Programs that have health plans in collaboration with pharmacies and pharmacists to improve star ratings metrics, primarily adherence metrics, are emerging in the marketplace. Thus, the feasibility of similar programs focused on POCT exists.
Conclusion

In view of the recent passage of the Patient Protection and Affordable Care Act, the pharmacy profession’s push for provider status, and the need for improved patient access to quality health care services (i.e., POCT programs), pharmacists are positioned to become more fully integrated within the U.S. health care system. However, with this opportunity comes the potential for further legislative and regulatory oversight, additional professional education requirements, increased administrative and financial burdens, workflow concerns, and even public scrutiny as pharmacists take on these expanded patient care roles. By being proactive in setting professional policy about participation of pharmacists and student pharmacists in POCT programs, the pharmacy profession will be in a better position not only to serve patients, but also to support the overall expansion of pharmacist-provided care.

References

Relevant APhA Policies

2013, 2008, 1987  
**Sale of Home-Use Diagnostic and Monitoring Products**
1. APhA supports the need to protect the health of people in the United States through proper instruction in the safe and effective use of the more complex home-use diagnostic and monitoring products.
2. APhA supports the promotion of pharmacists as widely available and qualified health care professionals to advise patients in the operation of home-use diagnostic and monitoring products.


2012, 2003  
**The Pharmacist’s Role in Laboratory Monitoring and Health Screening 2012, 2003**
1. APhA supports pharmacist involvement in appropriate laboratory testing and health screening, including pharmacists directly conducting the activity, supervising such activity, ordering and interpreting such tests, and communicating such test results.
2. APhA supports revision of relevant laws and regulations to facilitate pharmacist involvement in appropriate laboratory testing and health screening as essential components of patient care.
3. APhA encourages research to further demonstrate the value of pharmacist involvement in laboratory testing and health screening services.
4. APhA supports public and private sector compensation for pharmacist involvement in laboratory testing and health screening services.
5. APhA supports training and education of pharmacists and student pharmacists to direct, perform, and interpret appropriate laboratory testing and health screening services. Such education and training should include proficiency testing, quality control, and quality assurance.
6. APhA encourages collaboration and research with other health care providers to ensure appropriate interpretation and use of laboratory monitoring and health screening results.


2011  
**The Role and Contributions of the Pharmacist in Public Health**
In concert with the American Public Health Association’s (APHA) 2006 policy statement, “The Role of the Pharmacist in Public Health,” APhA encourages collaboration with APHA and other public health organizations to increase pharmacists’ participation in initiatives designed to meet global, national, regional, state, local, and community health goals.

(JAPhA NS52(4):482 July/August 2011) (Reviewed 2012)

1987  
**Pharmacist Training in Medical Technology 1981**
1. APhA supports the education and training of pharmacists in the ordering and interpretation of laboratory tests as they may relate to the usage, dosing, and administration of drugs.
2. APhA opposes requiring certification of pharmacists as medical technologists for the practice of pharmacy.


1989  
**Pharmacy-based Screening and Monitoring Services**
APhA supports projects that demonstrate and evaluate various pharmacy-based screening and monitoring services.

Relevant APhA-ASP Policy

2015.3 APhA-ASP Point-of-Care Testing
1. APhA–ASP supports state and federal legislation that allows pharmacists and student pharmacists to provide point-of-care tests and related clinical services—through appropriate protocol and in collaboration with other members of the health care team—to increase patient access to care and screen or monitor for indications requiring care follow-up, referral, or therapy adjustment.
2. APhA-ASP supports the incorporation of point of care testing education and training throughout the pharmacy curriculum to train student pharmacists on appropriate administration of tests and management of results, including but not limited to, relevant counseling, documentation, reporting, and follow-up.
3. APhA-ASP encourages the development of continuing education and training programs to enhance existing practitioner understanding and use of point of care testing.
4. APhA-ASP encourages all stakeholders, including, but not limited to, employers, patients, pharmacists, community pharmacies, health-systems, and third party payers to develop a compensation model recognizing the value and cost of pharmacist-provided point-of-care testing and the provision of related clinical services and is both financially viable and in the best interest of patients.
5. APhA-ASP encourages all public health stakeholders and agencies to promote patient awareness of pharmacist-provided point of care testing and related clinical services for the purpose of improving community surveillance of disease prevalence and incidence.
Policy from Related Organizations

**College of American Pathologists**

*Point of Care Testing Policy Synopsis*

Point of care testing (POCT) is defined as laboratory testing that takes place at or near the site where the patient is located. In order for a POCT program to provide quality patient care, it must be developed by all stakeholders, with guidance and leadership from pathologists, and consider cost-benefit analysis and appropriate technology. The application of new non-traditional technologies also should conform to these principles. Even for simple methods performed outside of the central laboratory, the expertise of pathologists and other laboratory professionals is essential for quality patient care.

**Policy**

Point of Care Testing (POCT) is any type of laboratory testing that takes place at or near where the patient is located. The College of American Pathologists (CAP) recognizes that POCT is an integral part of laboratory medicine and certain basic principles must apply: Quality of patient care and patient safety are the highest priorities. Therefore, POCT must meet the accreditation standards of the College of American Pathologists, or other accrediting agencies recognized by the Department of Health and Human Services. POCT should be under the supervision of the laboratory director to ensure quality of the testing and appropriate training of testing personnel. Development of these programs should actively involve all participants for either in-hospital or offsite testing, and should include laboratory staff, nursing, medical staff, administration, and other health care professionals. Efforts should be made to quantify and compare all costs and benefits associated with POCT and other testing modalities. Gathering of such data will allow optimal decision making regarding testing strategies. New technologies for testing non-traditional specimens or non-invasive measurements are likely to have growing application in point-of-care settings. In the interest of quality patient care, the application of new testing technologies should conform to the points listed above. Interoperability should be developed or expanded for existing and new POCT technologies to provide better oversight and incorporation of results into the electronic medical record.

**Revision History**

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Potential References for the Policy Committee

