

Laboratory Testing Presents Business Opportunities for Community Pharmacies

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The role of community pharmacies in health care has evolved and expanded in recent years. Many community pharmacies now offer health and wellness services related to identifying, preventing, and monitoring acute and chronic health care conditions. New developments in point of care testing technology have significantly broadened the number of available CLIA waived tests, and therefore have increased opportunities for community pharmacies to provide patient care services including point of care laboratory testing that takes place at or near the site where the patient is located. Pharmacies can collect specimens, conduct laboratory tests, interpret results, and make recommendations based on the results of screenings and diagnostic tests.

Community pharmacies are increasingly offering laboratory testing services to improve patient access to care and enhance pharmacy revenue. The number of pharmacies with CLIA waiver laboratory certificates of waiver increased 45% from 2015 to 2020. ([See U.S. Pharmacist, March 17, 2021](#)) To address the needs of their community, and its residents, community pharmacies can integrate laboratory services into health and wellness screenings and disease management services, including preventive health services, and other services that enhance patient access to care.

Community Pharmacy/Pharmacist Scope of Practice Expansions

COVID-19 Waivers

On May 12, 2020, California Department of Consumer Affairs Director (DCA Director) issued a [waiver](#) to allow pharmacists to order and administer Covid-19 tests in California. On August 25, 2020, the DCA Director issued a [waiver](#) to specified professional licensing requirements and amended the scopes of practice of pharmacists and pharmacy technicians to allow them to perform waived, point-of-care tests used to detect Covid-19. Along with

the waiver, the DCA Director released [guidance](#) to inform and educate pharmacies, pharmacists and pharmacy technicians of applicable clinical laboratory requirements.

Senate Bill 409

[Senate Bill 409](#), effective January 1, 2022, permanently codifies that 2020 waiver, and expands the types of clinical laboratory tests that a pharmacy/pharmacist may perform, effective January 1, 2022. Senate Bill 409 authorizes a pharmacist to perform any aspect of any FDA-approved or -authorized test that is classified as waived pursuant to CLIA and is either 1) used to detect or screen for specified illnesses, conditions, or diseases or 2) approved by the Board of Pharmacy in conjunction with the Medical Board of California and Laboratory Field Services division (LFS) within the California Department of Public Health (CDPH).

Community Pharmacy Authority to Provide Patient Care Services and Laboratory Testing

The authority for community pharmacies and pharmacists to order and administer tests resides in both provisions of Pharmacy Law as well as other provisions of the Business and Professions Code (BPC) related to the operations of clinical laboratories and authorized staff under the regulation of the CDPH LFS.

Skin Punctures and Patient Assessments. BPC [4052.4](#) establishes the authority for a pharmacist to perform skin puncture in the course of performing routine patient assessment procedures or any procedure authorized under BPC [1206.5](#) or BPC [1206.6](#). Routine patient assessment procedures mean procedures that a patient could, with or without a prescription, perform for him or herself (including temperature, pulse, blood pressure, respiratory rate, pulse oximetry and physical inspection), or clinical laboratory tests that are classified as waived.

Ordering and Interpreting Tests. BPC [4052\(a\)12](#) establishes the authority for a pharmacist to order and interpret tests to monitor and manage the efficacy and toxicity of drug therapies. The pharmacist performing such functions must ensure such testing is done in coordination with the patient's primary care provider or diagnosing prescriber, as appropriate.

Drug Therapy Related Laboratory Tests. BPC [4052.2\(a\)\(2\)](#) establishes the authority for a pharmacist to order drug therapy-related laboratory tests as part of the care provided in a licensed health care facility, licensed home health agency, licensed correctional clinic, a licensed clinic with physician oversight, or other provider as specified, in accordance with the policies, procedures, or protocols of that facility, home health agency, etc.

Performing and Interpreting Clinical Laboratory Tests. BPC [1206.5\(a\)\(11\)](#) establishes the authority for a pharmacist to perform a clinical laboratory test or examination classified as waived under CLIA as long as the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory director, as described in BPC [1209](#), including, but not limited to, documentation by the laboratory director of the adequacy of the qualifications and competency of the personnel. BPC [1206.6](#) provides authority

for pharmacist at a community pharmacy who, performs only blood glucose, A1c, or cholesterol tests that are classified as waived under CLIA in the course of performing assessments as provided in BPC [4052.4](#).

Pharmacy Authority to Use Pharmacists to Perform Clinical Laboratory Testing. BPC [4119.10](#) establishes the authority of a pharmacy to use pharmacist to perform CLIA waived laboratory tests as long as the pharmacy complies with specified criteria, including :

- The pharmacy is appropriately licensed as a laboratory under BPC [1265](#).
- The pharmacy maintains policies and procedures that do all of the following:
 - Establish training requirements, including specimen collection techniques relevant to a test being performed at the pharmacy, and ongoing training.
 - Establish safety precautions necessary to protect pharmacy staff and consumers and to reduce the risk of transmission, consistent with Cal-OSHA and CDC requirements, including, but not limited to, provisions for the use of personal protective equipment, cleaning and sanitizing procedures, appropriate biohazard waste requirements, and space requirements for pharmacy staff and consumers.
 - Ensure the availability of dedicated physically distanced space or other segregated space that provides for privacy during the testing process and private consultation with the pharmacist, and limits potential contamination in the pharmacy
 - Establish requirements for providing test results to the patient in a nonverbal manner, complying with mandatory reporting requirements to local and state reporting systems, and notifying the patient's health care providers if consent is provided, and referral to licensed sources of care for confirmation, diagnosis, and treatment as appropriate for follow up to positive test results.
 - Establish requirements for the pharmacist-in-charge (PIC) serving as the pharmacy laboratory director to report any reportable disease or condition identified in [Section 120130 of the Health and Safety Code](#) or the regulations adopted under that section.
 - Ensure documentation of testing equipment maintenance and calibration.
 - Ensure appropriate storage and handling of specimens, testing reagents, and other supplies or equipment that require specialized storage or handling. Specimen collection shall not include vaginal swab, venipuncture, or seminal fluid.
- The test is authorized to be administered by a pharmacist pursuant to BPC [4052.4\(1\)\(b\)](#).
- The PIC does both of the following:
 - Annually reviews the mandated policies and procedures, assesses the pharmacy's compliance with its policies, and documents corrective actions to be taken when noncompliance is found.
 - Maintains documentation of the annual review and assessment in a readily retrievable format for a period of three years from the date of completion.
- The pharmacy maintains documentation related to performing tests that demonstrates compliance with this section, which shall include the name of the pharmacist performing the test, the results of the test, and

communication of results to a patient's primary medical provider, and is maintained in a readily retrievable format for a period of three years from the date of creation.

Immunizations. Pharmacist may independently initiate and administer vaccines listed on the routine immunization schedules recommended by the federal Advisory Committee on Immunization Practices (ACIP), in compliance with individual ACIP vaccine recommendations, and published by the federal Centers for Disease Control and Prevention (CDC) for persons three years of age and older. BPC [4052.8](#) and [California Code of Regulations \(CCR\), Title 16, Section 1746.4](#). [Section 1746.4](#) requires the pharmacist to be certified in: a) administering immunization products by an approved and accredited program; b) administering basic life support, and c) completion of two hours of continuing education every two years. In addition, the pharmacist is responsible for maintaining documentation of the patient's vaccination, and to timely compliance with vaccination notification requirements for the patient and to the patient's primary care provider and state and/or local immunization information systems.

Laboratory Director. BPC [1265\(k\)](#) provides authority for the PIC to serve as the laboratory director for registration required under BPC [1206.6](#). A laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of competent qualified personnel and compliance with applicable laws.

CLIA Waived Laboratory Licensing Requirements

The Clinical Laboratory Improvements Amendments of 1988 (CLIA) is an amendment to the Public Health Services Act in which Congress revised the federal program for certification and oversight of clinical laboratory testing. A pharmacy that performs laboratory tests on human specimens for diagnosis or assessment must be appropriately licensed as a laboratory and have a CLIA certification or waiver. CLIA certification requirements vary depending on the complexity of the laboratory tests performed, from the least to the most complex: waived tests, moderate complexity tests, and high complexity tests. Waived tests are simple tests with a minimal risk for an incorrect result and are safe for home use or classified as non-prescription status.

Obtaining a CLIA Waiver to Perform Waived Tests

Obtaining a CLIA waiver is a two-step process requiring the submission of both Federal and State applications. The California State application is submitted to the California Department of Public Health (CDPH) Laboratory Field Services Division (LFS), is responsible for collecting and processing the federal and state applications through an online application process), which can be accessed [here](#) for more information on the application process). The LFS application submission consists of the CDPH online application and completed forms [CMS 116](#), [LAB 182](#), and [LAB 183](#).

Community Pharmacy CLIA Waived Laboratory Operational Issues

Patient Assessment

The patient should be assessed by the pharmacist or be assessed and referred to the pharmacy by another health care provider. The physical assessment should, at a minimum include temperature, pulse, blood pressure, respiratory rate, pulse oximetry, and physical inspection.

Laboratory Equipment

The laboratory director should assist the pharmacy in laboratory equipment selection to ensure that testing device(s) selected are appropriate for the testing desired and that the device meets quality of care goals and regulatory and/or accreditation requirements. Pharmacies should maintain documentation of laboratory testing equipment maintenance and calibration.

Quality Control

The laboratory director should make sure that the pharmacy develops and implements a quality management system to ensure that the laboratory testing process is safe, appropriate, and effective and that the laboratory testing provides accurate and reliable test results. All laboratory testing devices and tests should have their analytical performance verified to ensure the quality of results. In addition to laboratory testing device verification, document control, training and recertification of staff, audits and monitoring of quality indicators, and OSHA compliance should occur.

Written Policies and Procedures

The pharmacy will need to develop and implement written policies and procedures required by BPC [4119.10](#), and with regard to all tests performed in the lab. The policies and procedures should be readily available and followed by laboratory personnel.

Training

Pharmacy staff should be trained on specimen collection techniques, laboratory equipment operation and quality control. The National Association of State Pharmacy Associations offers a [Community Pharmacy based Point of Care Testing National Certificate Program](#) that includes 12 hours of home study and 8 hours of live training. The Centers for Disease Control (CDC) has published “Ready, Set, Test,” a booklet that describes recommended practices for providers performing patient testing under a CLIA Waiver Certificate. The CDC also offers an on-line training course corresponding to “Ready, Set, Test.”

Reimbursement for Laboratory Services

The pharmacy may obtain direct patient payment for laboratory testing or obtain contracts with third-party payers and seek separate reimbursements for the laboratory tests and for the pharmacist’s time. The pharmacy must be enrolled with CMS as a clinical laboratory in order to collect payment for laboratory testing under Medicare. The pharmacy will need to submit a [CMS-855B enrollment application](#) to the Medicare Administrative

Contractor (MAC) serving its geographic area, and upon approval, CMS will provide the pharmacy with a Provider Transaction Access Number (PTAN) for billing Medicare for CLIA waived tests as a clinical laboratory (a pharmacy can't bill for laboratory testing using its prescription drug PTAN number).

Pharmacy Business Opportunities In Laboratory Testing

Offering laboratory services for multiple purposes, including medication management, wellness and prevention, infectious disease screening, chronic disease screening, and chronic disease management, is another way community pharmacies can increase access to health care and improve public health. Further discussion of point of care testing business opportunities is provided below.

Health Wellness and Preventive Services

Community pharmacies can develop wellness and prevention services through laboratory testing for blood glucose, cholesterol, and A1c; and immunizations for influenza, COVID-19 (including booster), Shingles, Pneumonia (Pneumovax-23), Pneumococcal Conjugate (Prevnar), Tdap (Whooping Cough), Tetanus-Diphtheria (booster), Hepatitis B, Measles Mumps Rubella (MMR), Meningitis, Hepatitis A, Hepatitis A & B, Chickenpox (Varicella), Human Papillomavirus (HPV) or Meningitis. Health wellness and prevention programs also promote laboratory tests that screen for pregnancy, drugs of abuse, anemia, ovulation, conjunctivitis, myocardial infarction, inflammation, menopause, male fertility, serum chemistries (e.g., Sodium, Potassium), or lead poisoning. In addition, community pharmacies can provide tobacco cessation services, contraceptive prescriptions for women and dispense and administer naloxone. Additional pharmacy wellness and prevention services could include osteoporosis screening, weight management, pharmacogenomics, nutraceuticals, and hormone replacement.

Medication Management

Medication management services improves patient outcomes through improved medication use and reduction of the risk of adverse events. Community pharmacies can improve patient care by providing the following medication management services:

- Formulating a medication treatment plan
- Selecting, initiating, modifying, or administering medication therapy
- Individualizing drug dosing
- Monitoring and evaluating the patient's response to therapy
- Medication review to identify, resolve, and prevent medication-related problems, including adverse drug events
- Education and training designed to enhance patient understanding and appropriate use of his/her medications
- Support services and resources designed to enhance patient adherence with his/her therapeutic regimens

[Source, [APHA Foundation Medication Therapy Management](#)]

Infectious Disease Screening

Diagnosing infectious diseases promptly is important to provide patients with the most appropriate treatment in a timely manner. Community pharmacy laboratories can screen for the following infectious diseases and provide rapid results, thereby decreasing time to therapy for patients.

Adenovirus (Conjunctivitis)	Covid-19
Dengue	Ebola
Epstein Barr (EBV)	Group A Streptococcus (GAS)
Herpes Simplex	HIV
HPV	Influenza A/B
Malaria	Mononucleosis
Pneumoniae	Respiratory syncytial virus
Sexually transmitted diseases	Streptococcus pneumoniae
Tuberculosis	

Chronic Disease Screenings

Community pharmacists may use laboratory testing for chronic disease screenings to reach at-risk patients who do not see their physician annually or who lack a primary care provider or insurance. Community pharmacies can perform a variety of laboratory tests for chronic disease screening or management with the most commonly performed tests including those for cholesterol lipids, blood glucose, hemoglobin A1c, HIV, Hepatitis C, liver/kidney function, and substance abuse.

Based on the chronic disease screening findings, community pharmacies can refer patients to their primary care provider or a community health center; and educate patients about chronic disease risk factors and preventive health measures (e.g., diet, exercise, and social habits) that patients can undertake to reduce risks.

Chronic Care Management and Monitoring

Point of care laboratory testing aids in chronic disease management and monitoring. Community pharmacies can use laboratory testing to assist in the management and monitoring of chronic diseases such as diabetes, arthritis, hypertension, cardiovascular disease, and kidney function. Examples of laboratory tests that pharmacies can use to manage and monitor chronic disease are provided below.

Diabetes

- Hemoglobin A1c
- Lipid blood tests
- Fasting plasma glucose (FPG)
- Oral glucose tolerance tests (OGTT).

Arthritis

- Antinuclear antibody (ANA)
- Rheumatoid factor (R.F.)
- Anti-cyclic citrullinated peptide (anti-CCP)
- Uric Acid
- Erythrocyte sedimentation rate (ESR)
- C-reactive protein (CRP)

Hypertension

- Monitor blood pressure levels
- Electrolytes measurement
- Blood Urea Nitrogen (BUN)
- Lipid test for levels of various kinds of cholesterol
- Hormone tests of the adrenal gland or thyroid gland

Cardiovascular Disease

- Anticoagulation tests
- Thyroid function tests
- Lipid blood tests
- C-reactive protein
- Lipoprotein, homocysteine, and fibrinogen tests
- B-type natriuretic peptide test

Chronic Kidney Disease

- Serum Creatinine
- Glomerular Filtration Rate (GFR)
- Blood Urea Nitrogen (BUN)
- Urinalysis
- Urine Protein
- Microalbuminuria
- Albumin-to-Creatinine Ratio (ACR)
- Creatinine Clearance

Travel Health Services

Community pharmacies can provide international travel health services (including immunization, education, and treatment). Travel vaccines offered by pharmacies include typhoid, encephalitis, cholera, polio, rabies, and yellow fever vaccine; and travel medications include motion sickness prevention and Lyme disease prophylaxis. Prior to furnishing travel immunizations or medications, a pharmacist must perform a good-faith evaluation of the patient, including evaluation of the patient's travel history using destination-specific travel criteria. The travel history must include all the information necessary for a risk assessment during pre-travel consultation.

Conclusion

Community pharmacies are located in most communities in the United States, and more than 90% of the US population live within 5 miles of one, making community pharmacies readily accessible. Pharmacists are highly trained, and they can increase access to care by providing healthcare services for general health care conditions, and performing and interpreting diagnostic tests. Pharmacists should contribute to improving public health through patient care services, including laboratory and other services related to identifying, preventing, and monitoring acute and chronic health care conditions; immunizations, health and wellness screenings, medication monitoring, and patient counseling and education.

Hinshaw has a pharmacy law team that assists clients with pharmacy compliance and regulatory issues, including State Board of Pharmacy license applications, California Department of Public Health Clinical Laboratory license applications, and CLIA waiver applications. Please contact your Hinshaw attorney with any questions and for additional guidance on pharmacy regulatory and compliance matters.

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Michael A. Dowell

Partner

 213 614-7341

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