
Point-of-Care/CLIA Webinar Prep Series

Getting Your Pharmacy Started!



Webinar Prep Series

1. Overview
2. CLIA Application
3. CLIA Waived Equipment
- 4. Laboratory Director & Staff**
5. OSHA-Compliance
6. Policies and Procedures/Wrap Up

CLIA Laboratory Staff

- Laboratory director
- Pharmacy owner/manager
- Laboratory supervisor
- Laboratory technician
- Oversight physician

Laboratory Director Qualifications

Federal Regulations

- No defined qualifications for laboratories performing only waived tests

Pennsylvania (PA) Regulations

- Higher education and previous laboratory experience acceptable to the Department of Health required, either:
 - Doctoral degree (i.e. PharmD) + two years of experience
 - Masters degree (i.e. MS Pharm) + four years of experience
 - Bachelors degree (i.e. BS Pharm) + five years of experience

Laboratory Director Responsibilities

- Overall operation and administration of the laboratory
 - Including the employment of competent qualified personnel
- May delegate these responsibilities to other members of the pharmacy staff
- Ultimately responsible and must ensure that all the duties are properly performed and applicable CLIA regulations are met
- Responsible for ensuring that the laboratory develops and uses a quality system approach to laboratory testing that provides accurate and reliable patient test results

Quality Assurance

- Laboratory Director oversees development of the CLIA binder
 - A comprehensive and coordinated effort to achieve accurate, reliable, and timely testing services
 - This includes all of the laboratory's policies, processes, procedures, and resources needed to achieve consistent, high quality testing service
 - Ongoing monitoring of each testing process used in your laboratory in order to identify errors or potential problems that could result in errors
 - Corrective active taking and evaluation

Laboratory Director. The Centers for Medicare and Medicaid Services Website. <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/brochure7.pdf> . November 11, 2018.

Direct Oversight

- Must ensure that
 - Testing systems are appropriate for your patient population
 - Physical and environmental conditions of the laboratory are adequate and appropriate for the testing performed
 - Environment for employees is safe from physical, chemical, and biological hazards

Laboratory Director. The Centers for Medicare and Medicaid Services Website. <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/brochure7.pdf> . November 11, 2018.



Direct Oversight

- In addition
 - There are a sufficient number of appropriately educated, experienced, and/or trained personnel
 - Provide appropriate consultation, properly supervise, and accurately perform tests and report test results in accordance with the written duties and responsibilities specified by laboratory director
 - Each new test procedure is reviewed, included in the procedure manual and followed by personnel
 - Each employee's responsibilities and duties are specified in writing

Delegating Roles

- Remain actively involved in the operations of the laboratory to assure that others are performing the delegated duties appropriately
- Have a mechanism in place for effective communication among all personnel with regard to lab values and follow up
- Assure there is a process identified for corrective action and monitoring for erroneous results and critical lab values



Delegating Roles

- Evaluate quality assessment activities and include a mechanism for resolution of any complaints received against the laboratory, either from the staff, public or clients of the laboratory
- Review a sampling of proficiency testing (PT) results, ensure that PT samples are tested in the same manner as patient specimens and that the cause of PT failures are identified, corrected and documented
 - PT is not required for waived tests in PA
- Ensure that laboratory staff and management are aware of CLIA requirements and that all are properly trained

Other Responsibilities

- A person may assume multiple roles in the named CLIA requirements as the person meets the personnel qualification requirements of education, experience, and training for the position in order to fulfill the responsibilities
- Example
 - Laboratory Director may also operate as the Laboratory Supervisor

Laboratory Director. The Centers for Medicare and Medicaid Services Website. <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/brochure7.pdf> . November 11, 2018.

Top Ten Tips as a Laboratory Director

1. Learn CLIA www.cms.hhs.gov/clia and understand the laboratory director delegations
2. Review policies, procedures and processes
3. Review problem log and corresponding corrective actions
4. Monitor critical laboratory values
5. Notify the State Department of Health and the accrediting organization of the change in laboratory director
6. Review and evaluate the laboratory's quality assessment plan
7. Review the laboratory's proficiency testing (PT) quarterly
8. KNOW the equipment and test systems used in the laboratory
9. Verify that the supervisory and testing personnel are trained
10. Ensure that the laboratory is patient friendly 😊

Laboratory Owner

- Qualifications
 - Position not defined/required in federal regulations
 - No qualifications defined in state regulations
- Responsibilities
 - Proper maintenance and ethical operation of the clinical laboratory
 - Ensure laboratory is at all times under the direction of a director
 - Submit an annual report of the number and types of laboratory examinations performed to the Department
 - Notify the Department in writing of:
 - Changes in the directors or general supervisor within a 30-day period
 - Changes in all other technical personnel on a 6-month basis
 - Significant changes in physical facilities within 30 days after initiation of the changes

Laboratory Supervisor

- Qualifications
 - Position not defined/required in federal regulations
 - Same requirements as Laboratory Director outlined in PA regulations
- Responsibilities
 - Present on laboratory premises during all normal scheduled working hours in which tests are being performed
 - Provides direct supervision for the technical performance of the staff

Laboratory Technician

- Required to have earned a high school diploma or equivalent, and have documentation of training appropriate for the testing performed prior to analyzing patient specimens
- As such, student pharmacists, interns, pharmacy technicians, and other personnel in the pharmacy qualify as laboratory technicians and may operate point of care testing equipment



Laboratory Technician

- The technician must have been properly trained in patient preparation
 - Labeling, handling,, processing or preparation, transportation and storage of specimens
- Must exhibit skills required for implementing all standard laboratory procedures
- Must exhibit proficiency on each test method and for proper instrument use
- Must exhibit proficiency in preventive maintenance, troubleshooting, and calibration procedures related to each test performed
- Must exhibit working knowledge of reagent stability and storage
- Must be able to implement quality control policies and procedures of the laboratory
- Must have an awareness of the factors that influence test results

Oversight Physician

- Not required by federal or state law, but recommended as a form of external quality assessment
- The Physician Consultant may oversee the protocols established by the CLIA laboratory as described in the laboratory's policy and procedure manual
 - May review reports on a consistent basis prepared by the Laboratory Director regarding the laboratory technician-patient interface
 - Reports may include abnormal lab values, critical lab values, patient counseling, and follow-up
 - May review reports prepared by the Laboratory Director consistently regarding quality assurance of laboratory equipment

Oversight Physician

- Often times, a physician is contracted at a set amount of time and is compensated for his/her time for the CLIA laboratory
- The physician need not work directly at the pharmacy or have any other existing contracts
- The organization may wish to utilize a physician with an existing relationship
 - i.e. Standing order for immunization services
- The Consultant Physician will carry his/her own malpractice insurance with provision for coverage of outsourced practices.
- The Consultant should provide a copy of malpractice insurance and medical license for the laboratory binder

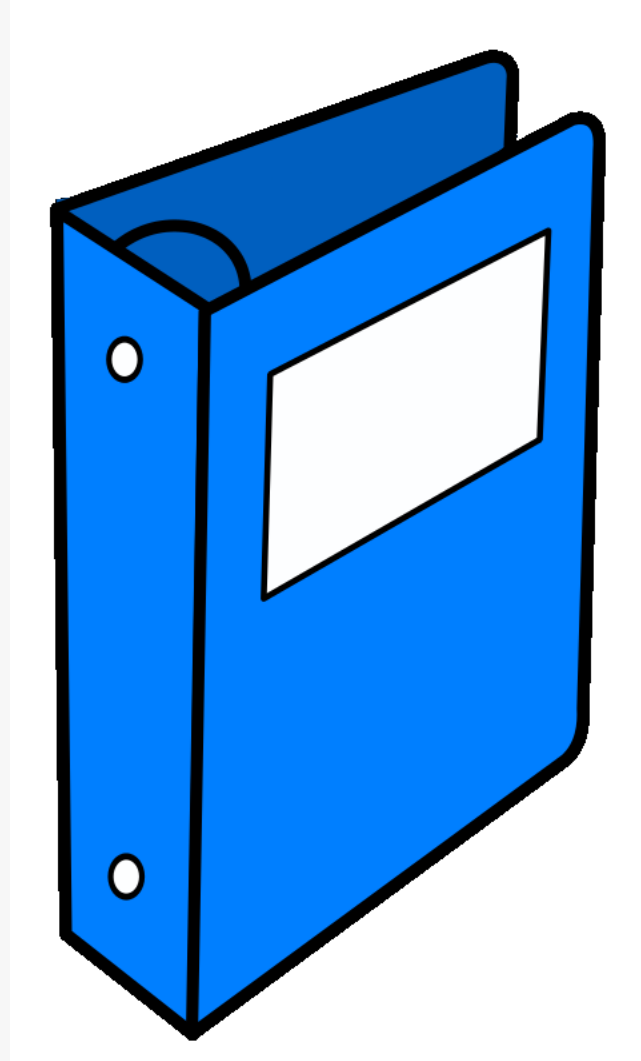
Next Steps to Consider

- Decide who will serve each role
- Define job responsibilities
- Create a Laboratory Binder



Components of a Laboratory Binder

- General Information
- Permits
- Consent forms
- Compliance and Training
- Policies and procedures
- Safety inspections
- Quality improvement/assurance
- Job descriptions



Next Session

Tuesday, December 10, 8:30-9:30a

CLIA Waived Equipment

Presenter: Luke Berenbrok

Register Now!

<https://bit.ly/2KReZYF>



Pennsylvania
Pharmacists
Association