UNDERSTANDING CLINICAL LABORATORY REGULATIONS IN PENNSYLVANIA

Under Pennsylvania's Clinical Laboratory Act and Department regulations, a clinical laboratory is a place, establishment or institution organized and operated primarily for the performance of bacteriological, biochemical, microscopical, serological or parasitological tests by the practical application of one or more of the fundamental sciences to material originating from the human body, by the use of specialized apparatus, equipment and methods, for the purpose of obtaining scientific data which may be used as an aid to ascertain the state of health. The term includes, but is not limited to, independent, hospital, industrial, state, county and municipal laboratories and clinical laboratories operated in private offices and clinics of practitioners of the healing arts (physician's office laboratory/clinic laboratory). A **physician's office laboratory** performs clinical laboratory testing only on its own patients or those of the practice; it does not receive specimens from other physicians' offices or laboratories. **Clinic laboratories** perform testing under the direction of the physician(s) who treat the clinic's patients; they do not receive specimens from other physicians, clinics or laboratories. Facilities only collecting or preparing specimens (or both) and not performing testing are not considered laboratories.

REQUIREMENTS FOR ALL LABORATORIES

Must hold a Pennsylvania Clinical Laboratory Permit issued by the Department of Health, Bureau of Laboratories.

Must hold a federal Clinical Laboratory Improvement Amendments (CLIA) certificate from the Centers for Medicare and Medicaid Services (CMS).

Must have a Director with a doctoral level degree with experience acceptable to the Department.

Must have a General Supervisor with education and experience as defined by the Department.

Must have a Director or General Supervisor present during all hours of testing. **See additional notes on page 5**.

Must ensure that all testing personnel are trained and maintain their competency to perform testing.

Must have written procedures for all tests performed (supplemented package inserts are acceptable).

Must have a written quality assurance policy which includes plans for the systematic monitoring and evaluation of the entire testing process.

Must use materials that are in date, stored and used according to the manufacturers' instructions.

Must record all quality control (QC) results so that they are traceable to the patient test results.

Must successfully participate in an approved proficiency testing program for those tests included on CLIA's regulated analyte list. The laboratory must instruct the program to "release results to the state agency". Must have a method to verify the procedure for non-regulated analytes two times a year.

Must notify the Bureau immediately of a change in director or location and within 30 days of a change in ownership, laboratory name or test menu.

Must obtain special approval from the Department's Division of Chemistry and Toxicology for any testing for drugs in blood and/or serum or urine, alcohol, blood lead or erythrocyte protoporphyrin.

Must retain all laboratory records for a period of 2 years (Immunohematology transfusion related records for 10 years, Cytology slides for 5 years and Histopathology reports and slides for 10 years).

Must agree that the Bureau reserves the right to perform an on-site inspection of the premises occupied and maintained by **any** laboratory at any time, and may examine all matters related to clinical laboratory testing.

Must adhere to any additional requirements defined by Department.

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APPLICATION PROCESS FOR ALL PENNSYLVANIA LABORATORIES

1. A laboratory must have both a federal CLIA certificate and a PA clinical laboratory permit (in most instances).
2. Complete and return a Clinical Laboratory Application together with a $100 initial filing fee. The federal CLIA application (CMS-116) must be included with the state application. CMS will bill the laboratory separately.
3. A copy of the director's curriculum vitae (CV), medical license, any board certifications (if applicable), and any CEUs (continuing educational units) (if applicable) must be included with the application. For the Department to qualify a director as a moderate or high complexity director under CLIA, additional documents may be required.
4. Annual licensure fees will be billed each year and must be paid by the invoice due date in order for a permit to be renewed (see fees below).

ADDITIONAL REQUIREMENTS FOR LABORATORIES APPLYING FOR A CLIA CERTIFICATE OF WAIVER (COW)

1. Once the above listed information is received by the Department and the CMS/CLIA fee has been paid, a laboratory permit will be issued.
2. Any CLIA-waived laboratory may be subject to an on-site inspection as part of a CLIA COW laboratory project.

ADDITIONAL REQUIREMENTS FOR LABORATORIES APPLYING FOR A CLIA CERTIFICATE OF PROVIDER PERFORMED MICROSCOPIC PROCEDURES (PPMP)

1. Once the above listed information is received by the Department and the CMS/CLIA fee has been paid, a laboratory permit will be issued.
2. The laboratory must enroll in a proficiency testing program or implement a policy for performing peer review at least twice per year for PPMP procedures.
3. Any CLIA-PPMP laboratory may be subject to an on-site inspection as part of a CLIA Certificate of PPMP laboratory project.

ADDITIONAL REQUIREMENTS FOR LABORATORIES APPLYING FOR A CLIA CERTIFICATE OF COMPLIANCE

1. Once the above listed information is received by the Department, a letter of acknowledgement will be sent to the laboratory indicating the need for an on-site survey. The laboratory may be given provisional approval to begin testing.
2. The laboratory must enroll in a proficiency testing program for CLIA regulated analytes. The laboratory must have a method to verify non-regulated analytes at least twice a year.
3. After approximately 90 days, a Lab Examiner will contact the laboratory to schedule an on-site inspection.
4. Once the laboratory is found to be in complete compliance with state and federal CLIA requirements, a clinical laboratory permit will be issued.

ADDITIONAL REQUIREMENTS FOR LABORATORIES APPLYING FOR A CLIA CERTIFICATE OF ACCREDITATION

1. Once the above listed information is received by the Department, a letter of acknowledgement will be sent to the laboratory indicating the need for an on-site survey. No testing may be performed until the laboratory has been notified by the Department that licensure is in effect.
2. The laboratory must enroll in a proficiency testing program for CLIA regulated analytes. The laboratory must have a method to verify non-regulated analytes at least twice a year.
3. The laboratory must provide a letter of acknowledgement from the accrediting organization to which it has applied.
4. A Lab Examiner will contact the laboratory to schedule an on-site inspection.
5. Once the laboratory is found to be in complete compliance with state and federal CLIA requirements, a clinical laboratory permit will be issued.

ADDITIONAL REQUIREMENTS FOR LABORATORIES PERFORMING TOXICOLOGY, BLOOD LEAD, OR ERYTHROCYTE PROTOPORPHYRIN TESTING

1. Laboratories requesting licensure to perform quantitative testing for drugs in blood and/or serum or urine, alcohol, blood lead or erythrocyte protoporphyrin must be approved by the Department's Division of Chemistry and Toxicology.
2. Laboratories performing this testing must be enrolled in the Pennsylvania Toxicology Proficiency Testing Program.
3. Once the above listed information is received by the Department, an invoice will be sent to the laboratory for all applicable proficiency testing fees.
4. Once the fees have been paid, pre-licensure proficiency testing specimens will be sent to the laboratory.
5. Once proficiency testing samples have been tested and results are found to be acceptable, a letter of acknowledgement will be sent to the laboratory indicating the need for an on-site survey.
6. The above requirements will be followed based on CLIA certificate type.

ANNUAL FEES

LICENSURE FEES:

Clinical Chemistry including Urinalysis	$100
Microbiology including Syphilis & Non-Syphilis Serology ……	$100
Hematology including Immunohematology ……	$100
Tissue Pathology including Exfoliative Cytology ……	$100
Radioisotope Technics ……	$100

PROFICIENCY TESTING FEES:
(See Division of Chemistry and Toxicology – Toxicology Proficiency Testing Program Fees)

Payment Options:

Payment may be made on-line with a credit card at www.PALabsBillPayment.health.pa.gov
or
Payment may be submitted by check or money order, made payable to the Pennsylvania Department of Health

MULTISITE CERTIFICATION/LICENSURE

CLIA allows for multiple laboratory locations to be covered by a single CLIA certificate. In order to apply for the CLIA multiple site certificate, the laboratories must meet one or more of the following regulatory exceptions:

- A laboratory that has temporary testing sites
- A not-for-profit or federal, state or local government laboratory engaged in limited public health testing (no more than a combination of 15 waived or moderate complexity tests) being performed at multiple testing sites
- A hospital with multiple testing sites located at contiguous buildings on the same campus within the same physical location or street address and under common direction

There is no provision in the Clinical Laboratory Act for multisite licensure. Each testing site must apply for and maintain a separate clinical laboratory permit.

LABORATORY PERMIT TO OPERATE SCREENING SITES

Screening sites are locations where certain tests are performed on a temporary basis. The following situations require a Pennsylvania clinical laboratory permit to operate screening sites:

- The collection and testing of specimens at temporary sites. An organization may visit the same site multiple times. However, testing supplies may not be stored at the site between visits.

An application to operate screening sites must be submitted to the Bureau along with supporting documentation. A screening site permit must be issued before patient testing may be performed.

LABORATORY PERMIT TO OPERATE A MOBILE LAB

A mobile laboratory is a movable, self-contained, operational laboratory with its own personnel, equipment, and records. Testing performed inside a vehicle which travels between temporary testing sites requires a laboratory permit to operate a mobile laboratory, not a permit to operate screening sites. A CLIA certificate is also required for the mobile laboratory. A vehicle which is only used to transport testing supplies/staff between temporary testing sites is not considered a mobile laboratory if no testing takes place inside the vehicle.

An application to operate a mobile laboratory must be submitted to the Bureau along with supporting documentation. A mobile lab permit must be issued before patient testing may be performed.

Note: If an organization performs testing at some temporary sites using a mobile laboratory and testing at other temporary sites without the mobile laboratory, it must obtain both a Pennsylvania clinical laboratory permit to operate a mobile laboratory and a permit to operate screening sites.

CLINICAL LABORATORY PERMIT CHANGES

The laboratory must notify the Bureau immediately of a change in director or location and within 30 days of a change in owner, laboratory name or test menu. To facilitate this process, the laboratory must complete and submit a Change of Status form to the Bureau of Laboratories. Once received, changes will be made to both the State permit and CLIA certificate, if applicable.

REQUIREMENTS FOR SUBMISSION OF A CMS 116 FORM

ALL LABORATORIES

- Change of ownership
- Certificate type change to PPMP, Compliance or Accreditation
- Adding a multiple site exception
- Personnel – Director (PPM, Certificate of Compliance)

REQUIREMENTS FOR SUBMISSION OF A CHANGE OF STATUS FORM

ALL LABORATORIES

- Change of director – Must also submit a copy of the director's medical license, CV and board certifications, if applicable
- Change of address (physical/mailing/billing)
- Change of laboratory name
- Change of ownership – You must also submit an updated CMS 116 Form
- Change of federal tax ID number
- Change of State permit type (ex. Physician's Office Lab to Independent Lab)
- Lab is closing or discontinuing all clinical testing
- Change of CLIA certificate type (ex. Waiver to Compliance) – If changing to PPMP, Compliance or Accreditation, you must also submit an updated CMS-116 Form

PHYSICIAN'S OFFICE LABORATORIES

- Change in test menu, such as adding and/or deleting tests – When adding a test, include the FDA 510(K) number
- Changing from a waived method to a non-waived kit/method for the same analyte (**NOT** changing from one waived kit/method to another)
- Changing from a non-waived method to a waived kit/method for the same analyte

ALL OTHER LABORATORIES

- Change in test menu, such as adding a ***category*** of testing (ex. Hematology, Clinical Chemistry) when the laboratory is not currently licensed to perform testing in that category or deleting a ***category*** of testing when the laboratory is authorized to perform unlimited testing in that category
- Change in any Toxicology testing, including adding and/or deleting tests ***and*** changing from one test method to another for the same analyte

Do **not** submit copies of procedures, validation studies, training documentation, etc. unless requested. Please maintain these documents to be reviewed at the time of your next on-site inspection.

The Change of Status Form must be signed by the director for a director change to be valid. For all other changes, the form may be signed by the director and/or owner of the laboratory.

PLEASE NOTE:
If your changes result in a change to your permit, you will receive a confirmation letter from the Department indicating the changes that were made. Please keep this letter with your records.

If your changes do not result in a change to your permit, your form will be filed. You will not receive a confirmation letter from the Department.

28 Pa. Code § 5.22(g) requires that a director be present for a reasonable period of each working day in each laboratory for which they are a director. The Department interprets the term “present” to include a remote/virtual (i.e., telephonic, email, video conferencing) presence, as well as a physical on-site presence.

For directors that will not have a daily, on-site physical presence, the Department requires that a plan be developed, signed, and submitted to the Department that demonstrates how the director will properly oversee the laboratory by remote/virtual means on days when they will not be physically present at the laboratory. The plan must, at minimum, include one monthly on-site visit to the laboratory. The monthly on-site visit combined with the daily remote presence enables the director to participate and actively oversee the planning, organization, direction and review of all laboratory operations to the extent necessary to ensure compliance with the regulations, including ensuring the proper storage and quality of reagents, supplies.