A Primer on Provider Performed Microscopy

Regulations, requirements, and recommended practices

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Introduction

Provider-performed microscopy (or PPM) procedures refer to a select group of microscopy tests commonly performed by healthcare providers during patient office visits. Suppose you are a provider or a clinical laboratory that performs testing on human subjects for any clinical purpose. In that case, you are subject to the Clinical Laboratory Improvement Amendments (CLIA) requirements of 1988, a federal law that the United States Congress passed in 1988. A CLIA Certificate for PPM procedures is required for a site where physicians and other providers perform PPM procedures as part of a patient's visit. The site CLIA laboratory director is responsible for overseeing PPM procedures at their site(s). These responsibilities include ensuring adequate training, periodic competency assessment, a functional quality management system, and coordination with regulatory agencies. CLIA requirements are enforced by the Centers for Medicare & Medicaid Services (CMS) and its accreditation agencies. Failure to do so can lead to erroneous test results, impaired patient care, and citations or fines during regulatory inspections. In addition, depending on the type and frequency of non-compliance, penalties may include cessation of Medicare and Medicaid payments. Ergo, the knowledge of requirements and recommended good practices around PPM are essential for anyone exploring supporting PPM in their practice.

What is CLIA and how is it enforced.

CLIA stands for the Clinical Laboratory Improvement Amendments (CLIA) of 1988, a federal law passed by the United States Congress that covers all clinical laboratory testing performed on human subjects, except for clinical trials and basic research. CLIA regulations can be found in Section 353 of Chapter 42 of the Code of Federal Regulation. The objective of CLIA is to ensure the accuracy, reliability, and timeliness of test results.

The scope of CLIA extends to any site that is performing any test for the diagnosis, prevention, or treatment of a disease. Based on CLIA regulations, tests are either considered waived or non-waived. Waived tests are simple to perform tests such as glucose meter testing and can be performed with minimal training. Nonwaived tests are more complex and are categorized as either moderate or high complexity based on criteria described in the CLIA regulations. Non-laboratory individuals can perform a subset of nonwaived tests, including PPM procedures, after formal and documented training. High complexity testing is usually reserved for laboratorians.

The Centers for Medicare & Medicaid Services (CMS) has the primary responsibility for the operation of the CLIA Program. Any provider or laboratorian performing any human testing must fulfill CLIA requirements and be prepared for announced or unannounced inspections by external inspectors. CLIA is a strict law; it identifies a wide range of violations. CMS and its accrediting agencies will act on any complaints from the public members, individual patients, and employees working at that site. In addition, CMS can impose alternative and principal sanctions. Failure to meet the CLIA requirements may result in the suspension of all or part of payments under Medicare and Medicaid.

What is a CLIA certificate.

Under CLIA, any site where providers or laboratorians perform any patient testing is considered a 'laboratory.' This definition includes a physician's office, inpatient floors, and any other site within the facility, including emergency rooms and labor and delivery suites. Each such site or 'laboratory' needs to be listed on an existing CLIA certificate or apply for a new certificate (CMS Form 116). Before any human testing can commence, one of the following CLIA certificates needs to be in place.

- Certificate of Waive.
- Certificate for PPM procedure.
- Certificate of Registratio.
- Certificate of Complianc.
- Certificate of Accreditatio.

Please note that a separate CLIA certificate is required for each site (street address) where you perform testing. You can have more than one CLIA certificate at a single street address. However, you cannot extend the same CLIA certificate to more than one street address unless you qualify for one of the exceptions listed here.

- Laboratories that are not at a fixed site, such as mobile units, health screening fairs, or other temporary testing sites, may be covered under the designated primary site or home base certificate, using its address.
- Not-for-profit or Federal, State, or local government laboratories that engage in limited public health testin.
- Laboratories within a hospital located at contiguous buildings on the same campus and under common direction may file a single application for the laboratory sites within the same physical site or street address.

What are PPM Procedures.

PPM procedures refer to microscopic examinations performed during a patient visit using specimens that quickly deteriorate or are not easily transportable. Therefore, PPM procedures are typically performed outside the traditional clinical laboratory and by individuals who are not laboratorians. In 1993, to address this class of testing, a subcategory of moderate complexity tests — physician-performed microscopy procedures- was created in CLIA. It allowed physicians to perform specific microscopic exams in addition to waived testing. Later, it was renamed to provider-performed Microscopy procedures to include other practitioners.

The PPM-certified testing site is restricted to nine specific microscopic examinations.

1. All direct wet mount preparations for the bacteria, fungi, parasites, and human cellular element. .
2. All potassium hydroxide (KOH) preparation.
3. Pinworm examination.
4. Fern test.
5. post-coital direct, qualitative examinations of vaginal or cervical mucou. .
6. Urine sediment examination.
7. Nasal smears for granulocyte.
8. Fecal leukocyte examination.
9. Qualitative semen analysis (limited to the presence or absence of sperm and detection of motility.

What is a Certificate for PPM Procedures.

A CLIA Certificate for PPM procedures is a certificate that permits physicians, qualified practitioners, and dentists to perform PPM procedures as part of a patient's visit. Providers must ensure that the PPM procedures at their site are covered under an existing CLIA certificate of accreditation. If this is not the case, the site must apply for CLIA Certificate for PPM. A site with a CLIA Certificate for PPM is not subject to routine surveys. However, if the site performs another nonwaived testing, it may need a CLIA certificate of accreditation. It will be subject to CMS, a State Agency, or a CMS-approved accreditation organization's biennial surveys.

Who is qualified to perform PPM Procedures.

Subpart M in the Code of Federal Regulations identifies the following individuals as qualified for PPM.

1. A physician includes an individual with a Doctor of Medicine, doctor of osteopathy, or doctor of podiatric medicine degree licensed by the State to practice medicine, osteopathy, or podiatry within the State in which the laboratory is located.
2. A practitioner including a nurse-midwife, nurse practitioner, or physician assistant, licensed by the State within which the individual practices if such licensing is required in the State in which the laboratory is located.

3. A dentist includes a Doctor of Dental Medicine or Doctor of Dental Surgery licensed by the State to practice dentistry within the State in which the laboratory is located.

Who is eligible to be a CLIA laboratory director?

To be eligible to be a CLIA laboratory director of a location provisioning PPM, an individual must be (a) a licensed physician, qualified practitioner, or dentist qualified to manage and direct the testing personnel and the performance of PPM procedures, (b) authorized to practice independently by the State, (c) have a current license as a laboratory director issued by the State where the laboratory or testing site is located if licensing is required, and (d) in most states, direct no more than five laboratories.

What are the roles and responsibilities of the CLIA laboratory director.

Under CLIA, the site performing PPM procedures must identify one individual as the CLIA laboratory director (hereafter referred to as Director) who shall be responsible for the overall operation and administration, including the employment of competent, qualified personnel. Even though the Director can delegate some of the responsibilities, the Director remains responsible and must ensure that all the duties are correctly performed and applicable CLIA regulations are met.

What are the roles and responsibilities of Providers.

Providers are responsible for specimen processing, test performance, and results reporting. Regulations require a written policy outlining testing that providers must follow. Additionally, providers must maintain and demonstrate competency. Before starting patient testing, the Director must ensure that all providers have completed a training program and be evaluated to demonstrate the skills and ability to work under the expected level of oversight during routine patient testing. Written procedures must be developed, approved, and updated for each PPM procedure performed at the testing site. Textbooks may supplement but not replace the laboratory's written procedures for testing. Policies must be readily available to all testing personnel. Each testing site should have site-specific procedures that follow local, State, and federal requirements for the safe disposal of biohazardous waste generated from specimen collection and testing.

Please note that medical staff credentialing cannot replace formal PPM training requirements. Training material should cover a broad menu of items, including but not limited to proper use and maintenance of the microscope, accurate performance of PPM tests, including the ability to detect and identify cellular elements, debris, and artifacts; quality control of stains and reagents, instrument maintenance, result-reporting, and quality and safety practices. Retraining must occur when problems are identified with performance. Training records must be retained for a minimum of two years.

The Centers for Disease Control and Prevention (CDC) Laboratory Training website (https://www.cdc.gov/labtraining/) offers numerous online training courses for the public health and clinical laboratory community free of charge. Additionally, other private sector vendors provide more online training and competency assessment tracking.

What are the requirements around Result Reporting?

Acceptable test result reporting requires all the following components (a) Patient identifier, (b) Test ordered/performed and provider's name/identifier, (c) Date/time of specimen collection, (d) Specimen source, when applicable, (e) Test result, and (f) Reference interval or interpretive notes, as appropriate.

Summary

For physicians, provisioning PPM service is a complex undertaking that is highly regulated by CLIA, CMS, and possibly the State. This complexity increases the providers' risk of inconsistent testing, increases compliance burden, and diverts resources from other clinical tasks. Therefore, in the long run, it is best to consider PPM as a constant balancing act where the need for immediate results must be balanced against the available resources. While designing and deploying a new PPM service, a physician-pathologist who already serves in the role in the role of the CLIA laboratory director could be go-to resource to understand and navigate the various CLIA requirements. When designed and deployed appropriately, PPM services can drastically improve patient experience and provider satisfaction. •

References

1. https://www.cdc.gov/clia/index.html
2. https://www.cdc.gov/labquality/ppm.html
3. https://www.cdc.gov/labquality/docs/pmp_booklet_7252019.pdf