CLINICAL LABORATORY IMPROVEMENT ADVISORY COMMITTEE (CLIAC)
CLIA CERTIFICATE OF WAIVER AND CERTIFICATE FOR PROVIDER-PERFORMED MICROSCOPY

MEETING SUMMARY REPORT

Workgroup Charge

The CLIA Certificate of Waiver (CoW) and Provider-performed Microscopy (PPM) Procedures Workgroup is charged with providing input to CLIAC for consideration in making recommendations to the Department of Health and Human Services (HHS) on the potential need for expanding regulatory oversight of CLIA CoW sites. The workgroup will also provide input to CLIAC on the potential need for expanded regulatory oversight of Certificate for PPM Procedures sites.

Workgroup Topics

1. Certificate of Waiver and Waived Testing

- What problems or concerns have you observed in Certificate of Waiver (CoW) laboratories that lead you to believe that increased oversight is needed?
    - What do you feel would ensure the quality of testing in CoW sites as related to:
      a. Laboratory Director
      b. Testing Personnel
      c. Inspections
      d. Proficiency Testing
      e. Facilities
      f. Quality System
      g. Safety Issues
      h. Following the manufacturer's instructions
- What are the reasons that the CLIA law should be opened to allow changes to the waived testing requirements under a CLIA CoW?
    - What other opportunities could be explored now to ensure the quality in CoW sites?
    - What avenues are available for expanding outreach to laboratories and healthcare providers?

2. Certificate for Provider-performed Microscopy Procedures

- Describe any challenges you have with complying with the CLIA regulations for PPMP tests.
- What problems or concerns in PPMP laboratories lead you to believe that increased oversight is needed?
    - Are changes needed to the required responsibilities of a Laboratory Director for PPMP?
    - Is the proposed list of providers permitted to perform PPMP tests appropriate?
    - Is there a need to amend the list of PPMP tests?
- The CLIA regulations currently allow for inspections of PPMP laboratories when deemed necessary for purposes listed in the regulations.
    - Should routine inspections be performed, and at what frequency?
    - In lieu of inspections, what alternative mechanisms for ensuring compliance with the existing applicable CLIA regulations could be considered?
- How should competency assessment requirements be tailored to a PPMP laboratory?
- How should quality control requirements be tailored to a PPMP test?
- What other opportunities could be explored now to ensure the quality in Certificate for PPM Procedure sites?
- What avenues are available for expanding outreach to laboratories and healthcare providers?

Workgroup Discussion and Comments-February 24, 2023

- Workgroup members completed the discussion of workgroup questions and finalized what would be included in the CLIAC workgroup presentation.

Workgroup Discussion and Comments- January 27, 2023

- Workgroup members agreed that routine inspections of PPMP sites should be considered along with virtual inspections.
- Consideration should be given to performing inspections on a 2-3 year cycle.
- A method to verify the patient collection process during an inspection must be determined.
- An alternative to site inspections would be to require continuing education for laboratory directors.
- One member expressed that PPMP sites should not be regulated.
- Members suggested using board certifications of providers to assess competency.
- PPMP testing must be performed in accordance with applicable requirements in subpart H, J, K, and M.
- Workgroup members were reminded of subpart K (493.1235) and (493.1236) of the CLIA regulations.
- One workgroup member suggested reviewing the six requirements for assessing competency and creating a subset for PPMP sites.

Workgroup Discussion and Comments- December 9, 2022

- Workgroup members were updated on the November CLIAC meeting that resulted in a recommendation to open the CLIA Law for Certificate of Waiver changes.
- A member reported that historically the intent of the PPMP regulations was not to have physicians perform competency.
- Provide an educational video on how to navigate the FDA-waived testing database should be created to help users.
- Complaint investigations have led to findings of PPMP laboratories/sites performing high-complexity and moderate tests that do not fall under PPMP and unqualified personnel performing testing.
- One workgroup member suggested adding technical consultant as required personnel under PPMP.
- Providers who work at multiple PPMP sites should only be required to perform competency assessments at one site.
- Stronger accountability is needed for the overall laboratory operation of PPMP sites.
- Consideration should be given to adding crystal analysis to the test list and expanding the primary instrument requirements to include dark-phase and polarizing light microscopy.
- Self-inspections rather than routine inspections can be used by laboratories/sites to ensure compliance.
- A member suggested limiting the number of certificates allowed due to a lack of resources to ensure compliance.
- Direct observation of specimen collection can be challenging to assess for competency.
- A member suggested proposing simulated patient specimens to replace direct observation for providers.

Workgroup Discussion and Comments- October 28, 2022

- A member provided data on CoW laboratory inspection findings from an accredited organization.
- Reports have shown that patient care decisions are being made based on erroneous CoW test results, so consideration should be given to opening the law as there is an obligation to act.
- Make tests more accessible for alternative sites, ambulances, and pharmacies. Make CoW tests available and safe.

- A member suggested that the CLIA Law should be open because it is now outdated. New technological advances, systems, and tests require the CLIA regulations to be updated.
- The FDA definition of waived tests should be updated.
- Tests need to be performed by trained personnel and in an environment with good laboratory practices.
- CoW sites do not have to notify CLIA when adding a new test. There is no oversight to ensure waived tests are being used in CoW laboratories/sites.
- Consideration should be given to updating the FDA CLIA currently waived analytes site to make the site easier to search for the test complexity.
- Manufacturers and sales representatives must do better notifying laboratories when a test's complexity changes from waived to moderate or high.
- There is a current need to update the CLIA law because there is non-compliance with the current law and no way to oversee it.
- One member suggested incorporating penalties for larger health systems with smaller clinics. The accountability should fall on the institution when it comes to non-compliance.
- Provide educational resources to anyone who submits a CLIA application.
- Communicating with CoW sites/laboratories can be challenging because the CLIA application does not make email addresses a required field.
- One member suggested requiring the director to speak directly with a surveyor to understand the responsibilities of having a CoW.
- Self-inspections rather than traditional inspections can be used by laboratories/sites to ensure compliance and a way to acknowledge that the process is understood.
- A member agreed with having sites perform self-inspections as a way for CoW laboratories to take on some responsibility for compliance.
- Require a laboratory director to sign off on an attestation when a self-inspection is completed.
- A way to get information out is to consider who is performing the waived tests and reach out to those professional organizations.
- Look back at lessons learned during COVID-19 on how outreach expanded.
- The number of CoW non-compliance laboratories is unknown because the current law doesn't allow for the oversight needed to ensure compliance.

PPMP Introduction Discussion

- Providers and mid-level practitioners see PPMP tests more as physical exams than laboratory tests.
- Consideration should be given to requiring only one competency when providers and mid-level practitioners travel between multiple sites within a large health system.
- There should be consideration given to not requiring competency for board-certified physicians/providers when there is evidence of training.
- It is necessary to reiterate to applicants that laboratory technicians cannot do testing for PPMP sites.
- One member stated that it is too hard and complex to maintain compliance with a PPMP certificate.

Workgroup Discussion and Comments- October 14, 2022

- Members suggested having CoW inspection data to decide whether or not inspections would be beneficial.
- More communication is needed for the general public to understand that a CLIA certificate is needed to perform testing.
- There are currently various and creative ways to inspect without being face to face (virtual and self-inspections)

- There should be consideration given to requiring self-inspections with a checklist or initial inspections before certificates are issued.
- The need for inspections should lie with the laboratories and sites that don't already have inspections. It is unnecessary for the CoW labs associated with a hospital system to be inspected when the CoW is affiliated (or under the umbrella of) with a healthcare system that has surveys performed by an accreditation organization (i.e., TJC or CAP).
- Proficiency testing for nonregulated waived tests would be considered a burden for laboratories.
- There are a lot of unregulated tests that do not require PT but would require a twice annual verification.
- Proficiency testing is expensive in the form as it exists now and not like actual patient testing.
- One member suggested requiring CoW laboratories to perform proficiency testing will be burdensome.
- Competency Assessments (CA) would be more preferable, however separate CA per site is not desirable.
- There is a need for CLIA to have a minimum requirement for facilities, especially when considering molecular waived testing.
- A major concern should be how CLIA ensures quality in testing at physician office laboratories (POL).
- A member suggested partnering with manufacturers as a way to educate users on performing quality testing.
- Require manufacturers to submit safety considerations with the package insert to ensure laboratories know how to address safety issues.
- Provide a template standard operating procedure that demonstrates how to outline the manufacturer's instructions to laboratory directors.
- Manufacturers need to make the instructions for use more accessible (i.e. larger text) to users.
- Learning modules for training, in person demonstration with a preceptor.
- Procedural drift: even if they know the procedure people drift from procedures as time goes on.
- Waived tests users are taking the manufacturer's instructions and translating it into another platform for training. That translation is only as good as the person who performs the translation.
- When procedures are updated by the manufacturers, those updates should clearly be communicated to the end user.
- Encourage engineering controls that mitigate human behaviors.
- A member stated that they are not in favor of writing SOPs.

Workgroup Discussion and Comments- September 23, 2022

- There may be many nontraditional places that do not realize that they need a CLIA certificate to perform testing. These sites may not be familiar with the CLIA regulations, including the requirement to follow the manufacturer's instructions.
- There should be clear, separate requirements for verification, validation, and training.
- Many of the staff performing waived testing do not have any experience in a laboratory or performing laboratory testing in medical facilities. It is difficult to expect staff to understand laboratory testing if they do not have any previous experience. It is important for staff to have the appropriate training to be able to answer questions, educate patients, and understand the CLIA regulations.
- Laboratory terminology is not clear to individuals who have not been laboratory trained. Certificate of Waiver laboratories should identify someone who is laboratory trained to help them understand standards and quality when it comes to laboratory testing.
- Contacting and communicating with CoW laboratories can be challenging. There should be an easy way to follow up to ensure sites are performing testing correctly under the appropriate conditions.
- More education on roles and responsibilities for personnel directly involved in the laboratory is needed.

- There should be consideration given to the expansion of waived testing and that molecular-based tests are now being categorized as waived.
- Implementation of standards for journals when publishing off-label information about a test to include a disclaimer that off-label use would require high-complexity testing oversight in a CLIA laboratory is needed.
- There is a need for laboratory directors/owners to have educational requirements to understand all the testing responsibilities before sites are granted a CoW.
- Sending the CDC Ready? Set? Test! booklet to new applicants could be beneficial in ensuring new certificate holders know the guidelines.
- There should be more pathways to obtain training to allow people to do the right thing.
- CDC's laboratory training page should be considered if a requirement to increase training of the laboratory director or testing personnel is implemented.
- A member suggested having a laboratory director certificate program as a way to certify laboratory directors.
- Standards and expectations should be required for CoW laboratory directors, such as certification requirements.
- Increasing the frequency of inspections, maybe not the same frequency for high complexity and moderate complexity testing. Requirements for proficiency testing and facilities are also needed.
- Consideration should be given to allow surveyors to perform onsite inspections after the CoW application is received to ensure quality testing.
- Providing more understanding of laboratory processes to those performing the test in a CoW laboratory will help with the overall quality of testing.
- Provide a baseline standardized understanding of some of the basic principles of quality management at the point-of-care.
- Train personnel on the things they need to know about laboratory testing in general to give accurate results.
- A member commented that some of the waived tests being approved by the FDA were not that "simple."

Workgroup Agreements (Ongoing List)

- There is a need for specific training requirements for testing personnel and a standard training program.
- Proficiency testing (PT) is of limited use and not favorable due to the expense of purchasing modules for the large number of sites performing CLIA-waived testing.
- The CLIA law should be opened to allow more oversight for CoW laboratories/sites.