LABORATORY CERTIFICATION REQUIREMENTS FOR WISCONSIN TREATMENT COURTS AND PROGRAMS

PURPOSE

Wisconsin treatment court programs are required to obtain a Clinical Laboratory Improvement Amendments (CLIA) certificate to perform laboratory testing. This is required when the drug or alcohol testing is used for individual client assessment or treatment. Treatment programs may encompass adult drug courts, hybrid courts, intoxicated driver programs, mental health courts, juvenile drug courts, family dependency courts, and veteran courts. Providers found to be performing such testing without a CLIA certificate are in violation of CLIA and subject to possible federal enforcement actions.

REQUIREMENTS

The definition of a laboratory at 42 CFR § 493.2 means a facility that examines materials derived from the human body for the purpose of providing diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances in the human body.

Therefore, any entity or facility performing drug or alcohol testing, such as screening or confirmatory testing, where the test results are used for the purpose of referring, offering, or making available to the test subjects treatment, must obtain an appropriate CLIA certificate or cease testing. The CLIA program is a federal program administered by the Centers for Medicare and Medicaid Services (CMS) that encompasses any provider performing laboratory testing.

TEST COMPLEXITY AND CLIA CERTIFICATE TYPE DEFINED

To determine the CLIA certificate type needed to perform testing, the complexity of the test will need to be determined. Test complexity is categorized by the Food and Drug Administration (FDA) into waived, moderate, and high.

Waived Test Complexity

In most cases laboratories will be performing rapid screening tests using test systems that have been categorized as "waived" by the FDA. As defined by CLIA waived tests are categorized as "simple laboratory examinations and procedures that have an insignificant risk of an erroneous result when performed correctly." Waived test systems require a CLIA Certificate of Waiver (COW). Waived testing only requires that the manufacturer's package insert instructions are followed per the federal CLIA regulations. The benefits of waived testing include regulations that are easy to follow, results that are usually readily available within a matter of minutes, minimal training, and easy to perform testing in nontraditional settings. There are no routine inspections with COW; however, CMS has authorized inspections under certain circumstances, such as complaints and to obtain information about waived testing. State agencies are authorized by CMS to perform educational surveys of 2% of COW labs each year.

Moderate or High Test Complexity

Test systems using non-waived test methodologies will require a Certificate of Compliance (COC) or Certificate of Accreditation (COA). Non-waived tests are classified by the FDA as moderate or high complexity. Test systems that use analyzers are often categorized at a higher complexity level. Moderate

or high complexity testing laboratories are required to follow the entire CLIA regulations. Laboratories are surveyed for compliance to the full set of CLIA regulations every two years.

Test complexity may be determined at the following link in the FDA website:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfclia/search.cfm

Manufacturer package inserts for testing products often provide test complexity information. If a package insert states, "For Forensic Use Only," this means that the FDA has not categorized this test for CLIA purposes and, therefore, the test defaults to high complexity. A COC or COA is needed to perform high complexity testing.

Manufacturer websites may state that a product is classified as CLIA-waived. Websites are not acceptable forms of evidence for test complexity determination. Only information from the FDA test complexity database or a manufacturer's package insert is acceptable.

DIRECTIONS

Contact the Licensing, Certification, CLIA Section for questions, CLIA application requests, and assistance with regulatory interpretation at 608-261-0654 or dhsdqaclia@dhs.wisconsin.gov.

RESOURCES

1. Federal CLIA Regulations and Interpretive Guidelines
   http://wwwn.cdc.gov/clia/Regulatory/default.aspx

2. CMS Survey and Certification Memo 08-35, *Drug or Alcohol Screening/Testing and CLIA Certification*
   https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/SCLetter08-35.pdf

3. FDA Test Categorization Database
   http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/Search.cfm

4. CMS CLIA brochure, *How to Obtain a Certificate of Waiver*
   https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Brochures.html

5. *CLIA Application for Certification* (CMS-116 Form)
   https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/CMS-Forms-Items/CMS012169.html

6. Center for Disease Control and Prevention (CDC) booklet, *Ready? Set? Test!*
   http://wwwn.cdc.gov/clia/resources/waivedtests/pdf/readysettestbooklet.pdf