CLIA Waived Information

Overview / Background

Congress enacted the Clinical Laboratory Improvement Amendments ("CLIA") in 1988 to ensure the accuracy and reliability of all laboratory testing. This legislation, for the first time, extended federal regulation to all laboratories that perform testing on human specimens for the purpose of diagnosing or treating disease, illness, or assessment of human beings. The objective of the CLIA program is to insure quality laboratory testing.

Prior to CLIA, federal regulation of laboratory testing was limited to testing performed in independent laboratories and hospitals. The CLIA statute extended regulation to all types of testing sites and based regulation on the complexity of tests, not the type of lab where the testing occurs. Thus, laboratories performing similar tests must meet similar standards, whether located in a hospital, doctor's office or other site.

CLIA requires all entities that perform even one test, including a CLIA waived test on…"materials derived from the human body for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of human beings" to meet certain Federal requirements. If an entity performs tests for these purposes, it is considered under CLIA to be a laboratory and must register with the CLIA program.

All clinical laboratories must be properly certified to receive Medicare or Medicaid payments.

On September 5, 2008, CLIA released a memorandum that restates an ongoing policy that laboratories performing drug or alcohol screening and/or testing followed by individual treatment must be CLIA certified.

State survey agencies, typically state health departments are responsible for oversight of the CLIA program.

CLIA established three categories of laboratory tests: waived tests, moderately complex tests, and highly complex tests. Waived tests – simple tests with small chance of error or risk are exempt from virtually all CLIA rules, so long as testing is performed in strict compliance with the manufacturers' instructions. Moderate and high complexity tests are subject to regulations setting minimum qualifications for all persons performing or supervising these tests. These laboratories must also participate successfully in approved proficiency testing programs.

CLIA Waived Tests and Facilities

By the CLIA law, certificate of waiver (COW) laboratories perform only tests that are determined by the FDA or CDC to be so simple (CLIA Waived) that there is little risk of error.

The COW laboratories must meet only the following requirements under CLIA:
a) Enroll in the CLIA program;
b) Pay applicable certificate fees biannually; and
c) Follow manufacturers test instructions.

Application for a CLIA Certificate
The Centers for Medicare and Medicaid Services (CMS) has made available the Clinical Laboratory Amendments Application for certification Form, CMS-116. This form should be completed and mailed to the address of the local state Agency for the state in which the testing will be performed. For additional details contact Drug Test Systems or visit www.cms.hhs.gov/CLIA/06.