

# Clinical Laboratory Improvement Amendments for ACHs

*Guest article by Deborah Strum, NCALTCF Board Member and owner of Grandview Manor in Franklin.*

## **What is CLIA and are you a Lab?**

The Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA). In total, CLIA covers approximately 200,000 laboratory entities. The Division of Laboratory Services, within the Survey and Certification Group, under the Center for Medicaid and State Operations (SMSO) has the responsibility for implementing the CLIA Program.

The objective of the CLIA program is to ensure quality laboratory testing. Although all clinical laboratories must be properly certified to receive Medicare or Medicaid payments, CLIA has no direct Medicare or Medicaid program responsibilities.

## **Are you a lab?**

CLIA requires every facility that tests human specimens for the purposes of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, a human being to meet certain Federal requirements. If your facility performs test for these purposes, it is considered under the law to be laboratory. CLIA applies even if only one or a few basic tests are performed and even if you are not charging a fee for testing. In addition, the CLIA legislation requires financing of all regulatory costs through fees assessed to affected facilities.

## **What does this allow you to do?**

First, determine the complexity of the tests you will perform in the laboratory; some tests are considered “waived”. Fingerstick glucose and dipstick urinalysis are just a few of the simple tests classified as waived. No inspection or proficiency testing is required, but you must follow the manufacturer’s directions for the test. Labs that only perform waived tests are called waived labs.

The CLIA amendments of 1988 specified that laboratory requirements be based on the complexity of the test performed and established provisions for categorizing a test as waived. In the regulation, waived tests were defined as (1) simple laboratory examinations and procedures that are cleared by the Food and Drug Administration for home use; (2) employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or (3) pose no reasonable risk of harm to the patient if the test is performed incorrectly.

The specified tests that are listed in the regulation as waived are:

- Dipstick and tablet reagent urinalysis (non-automated) for the following: bilirubin, glucose, hemoglobin, ketone, leukocytes, nitrite, pH, protein, specific gravity, and urobilinogen.
- Fecal occult blood
- Ovulation tests – visual color comparison tests for luteinizing hormone
- Urine pregnancy tests - visual color comparison
- Erythrocyte sedimentation rate (non-automated)
- Hemoglobin-copper sulfate (non-automated)
- Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use
- Spun microhematocrit

- Hemoglobin by single analyte instruments with
- self-contained or component features to perform specimen/reagent interaction providing direct
- measurement and readout

In November 1997, the CLIA waiver provisions were revised by Congress to make it clear that tests approved by the FDA for home use automatically qualify for CLIA waiver. Professional use versions of professional versions do qualify for expedited waiver review.

There are 28 types of laboratories. Listed are some of the more-common types of certified laboratories: independent labs, hospitals, physician office labs, home health, hospice, industrial (employee health), pharmacy, school/student health, ambulance, skilled nursing facilities/nursing facilities, ambulatory surgery center, assisted living facility, dialysis facility, intermediate care facility for mentally retarded, prison, public health laboratory, health fair, etc.

**But do I have to?**

There are criminal penalties for willful disregard of this law and financial penalties for failure to appropriately apply the law. See insert for form application.

**What should you do?**

You must apply to the NC Division of Health Service Regulation, Acute and Home Care Licensure and Certification Section using CMS-116 form (enclosed). North Carolina does not have its own licensing laws but uses the CLIA regulations for laboratories and laboratory personnel.

The form is also available from the Centers for Medicare and Medicaid Services (CMS) Web site for CLIA: [www.cms.hhs.gov/clia/cliaapp.asp](http://www.cms.hhs.gov/clia/cliaapp.asp). Also find a complete list of waived lab tests and online education