Clinical Laboratory Improvement Amendments (CLIA) Waivers

Every public school that does even one lab test needs to have a CLIA waiver. If a student is independently performing all testing, e.g. blood glucose monitoring, a waiver is not needed for that testing device. However, if the student needs any assistance with performing the test, *such as applying the blood to the stick or inserting the stick into the device*, a waiver is needed. (This does not include interpretation of the test).

The Law (Public Law 100-578)

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) law specified that laboratory requirements be based on the complexity of the test performed and established provisions for categorizing a test as waived. Tests may be waived from regulatory oversight if they meet certain requirements established by the statute. The section of the statute specifying criteria for categorizing a test as waived was excerpted in the regulations at 42 CFR 493.15(b) and 493.15(c). A list of the waived tests is given below.

The Regulations (42 CFR part 493)

On February 28, 1992, regulations were published to implement CLIA. In the regulations, waived tests were defined as simple laboratory examinations and procedures that are cleared by the Food and Drug Administration (FDA) for home use; employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or pose no reasonable risk of harm to the patient if the test is performed incorrectly.

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

1. Dipstick or Tablet reagent urinalysis (non automated) for the following:
    - Bilirubin
    - Glucose
    - Hemoglobin
    - Ketone
    - Leukocytes
    - Nitrite
    - pH
    - Protein
    - Specific gravity
    - Urobilinogen
2. Fecal occult blood
3. Ovulation tests - visual color comparison tests for luteinizing hormone
4. Urine pregnancy tests - visual color comparison tests
5. Erythrocyte sedimentation rate-non-automated
6. Hemoglobin-copper sulfate - non-automated
7. Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use

8. Spun microhematocrit
9. (added 1/19/93) Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout.

A complete list of the waived tests can be found at www.cms.gov/clia under the heading "Categorization of Tests."

Background Information

A laboratory is any facility (including schools) that does laboratory testing on specimens derived from humans to give information for the diagnosis, prevention, treatment of disease, or impairment of, or assessment of health.

The categorization of commercially marketed *in vitro* diagnostic tests under CLIA is the responsibility of the FDA. This categorization includes the process of assigning commercially marketed in vitro diagnostic test systems to one of three CLIA regulatory categories based on their potential for risk to public health:

- waived tests
- tests of moderate complexity
- tests of high complexity

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 home use tests qualify for expedited waiver review since only the differences between the home use and professional use versions need to be examined to determine whether the professional version qualifies for waiver.

To summarize, under the current process, a waiver may be granted to: 1) any test listed in the regulation, 2) any test system for which the manufacturer or producer applies for waiver if that test meets the statutory criteria and the manufacturer provides scientifically valid data verifying that the waiver criteria have been met, and 3) test systems cleared by the FDA for home use.

The Process

Most schools that perform testing use tests listed in the waived category.

Public Schools can apply as a school district for a CLIA Waiver because they are state government entities. Private schools apply separately for each school. If the school has a microscope and performs tests not listed on the waiver list, the independently licensed providers (MD, DO Pa or CNP) who perform tests using the microscope will need Provider Performed Microscopy (PPM) Certificate instead of a Certificate of Waiver. Waived tests may be performed under all certificate types.

There is a CDC online course (and booklet) that every person (including health assistants / UAPs) who perform waiver tests should view. It is called, "Ready, Set, Test," and is worth one CME credit. The website is listed below. Nurses and HAs need to click on the registration tab and register first before taking the course.

School districts apply for the waiver using the **CMS116 form** and the application costs $150 every other year. The school district must list what tests they are performing at schools on the application including the name of the drug testing kits, if their school is using them, because some drug testing kits are not on the waiver list. For home blood glucose monitors brought by students, it is acceptable to enter "various blood glucose monitoring tests" on the form. **For each home glucose monitoring device used by a student, a copy of the test instructions needs to be on file at the school.**

MSBS funds can be used to pay for the application.

References

- http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/How_to_Apply_for_a_CLIA_Certificate_International_Laboratories.html
- http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/waivetbl.pdf
- http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS116.pdf
- http://wwwn.cdc.gov/clia/Resources/WaivedTests/default.aspx
- https://cdc.train.org/DesktopModules/eLearning/CourseDetails/CourseDetailsForm.aspx?tabid=96&courseid=1033476
- http://wwwn.cdc.gov/clia/Resources/WaivedTests/pdf/ReadySetTestBooklet.pdf
- http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIA_certificate_fee_schedule.pdf

For questions in New Mexico contact:
Julie Aragon, CLIA Program
Health Facility Licensing & Certification Bureau
Bank of the West Building
5301 Central Avenue NW, Suite 400
Albuquerque, NM 87108 (505) 222-8646 FAX: (505) 841-5834
e-mail julie.aragon@state.nm.us
Internet: http://dhi.health.state.nm.us/index.php

How to Apply

1. Complete the application (attached) with a detailed list of tests that will be performed in your District.

Please include the name of the test, test system used, and the CPT code used for billing. This information will ensure that the correct CLIA certificate will be issued. Please include a form of address verification such as incorporation documents, utility bills, lease agreements or business license.

For home blood glucose monitors brought by students, it is acceptable to enter "various blood glucose monitoring tests" on the form.

2. Send the completed application packet to:

CLIA Program
5301 Central Ave NE
Suite 400
Albuquerque, NM 87108
Fax (505) 841-5834

DO NOT SEND MONEY WITH THE APPLICATION
All checks will be returned. CMS in Baltimore will bill the facility for all fees.

3. You will be notified by phone or by mail if the application is incomplete or inaccurate.

4. Once the fees have been paid, CMS will issue the appropriate certificate.

http://dhi.health.state.nm.us/index.php