How to Obtain a CLIA Waiver and Begin Testing

Background:

Recently, the Idaho Board of Pharmacy updated the definition of “pharmaceutical care services” to include “ordering and interpreting laboratory tests.” This rule change took effect on March 25, 2016. While the definition was broad, most pharmacies nationally focus primarily on CLIA-waived tests, such as those for glucose, cholesterol, influenza, and strep throat, among others.

What is CLIA?

In 1988, Congress passed the Clinical Laboratory Improvement Amendments (CLIA) for non-research laboratory testing. CLIA established quality standards for laboratories to ensure the accuracy, reliability, and timeliness of patient test results, regardless of where the test is performed.

CLIA regulations apply to laboratory testing in all settings, including commercial, hospital, and physician office laboratories of materials derived from the human body for the purpose of diagnosis, prevention, treatment, or the assessment of the health of human beings. CLIA requires the U.S. Department of Health and Human Services to certify and mandate all operating laboratories performing non-research testing to have a CLIA certificate and meet applicable federal requirements.

How does the federal government oversee CLIA?

Several federal agencies have specific roles in the administering quality laboratory services. The table below -- adopted from the CDC -- describes the responsibilities of each agency's role.

Federal Agency	Responsibilities
Centers for Medicare and Medicaid Services (CMS)	❏ Approves private accreditation organizations that perform inspections and approve state exemptions ❏ Collect user fees ❏ Conduct inspections ❏ Enforces regulatory compliance ❏ Issue laboratory certificates ❏ Publishes CLIA rules and regulations
Food and Drug Administration (FDA)	❏ Categorizes tests based on complexity ❏ Develops rules and guidance for CLIA complexity categorization ❏ Reviews requests for Waiver by Application
Centers for Disease Control and Prevention (CDC)	❏ Conducts laboratory quality improvement studies ❏ Develops and distributes professional information and educational resources ❏ Develops technical standards and laboratory practice guidelines ❏ Provides analysis, research, and technical assistance

How does the state government oversee CLIA?

Idaho Bureau of Laboratories (IBL) is organizationally structured within the Idaho Department of Health and Welfare Division of Public Health. The IBL regulates over 1,000 clinical labs across the state, including hospitals, clinics, doctor's offices, and long-term care facilities. Under 56-1003, Idaho Code, the Idaho Legislature has delegated to the Board of Health and Welfare, the authority to set standards for laboratories in the state of Idaho (IDAPA 16.02.06). The State of Idaho requires all laboratories performing diagnostic testing in the state to be registered with the Lab Improvement Section at IBL. IBL is also under contract with the Centers for Medicare & Medicaid Services (CMS) to oversee the CLIA Laboratory Program for the State of Idaho.

What is a CLIA-waived test?

As defined by CLIA, waived tests are categorized as "simple laboratory examinations and procedures that have an insignificant risk of an erroneous result." In other words, the tests are so easy and accurate that little risk of error exists when done correctly. Any person who obtains a CLIA certificate of waiver (CoW) may perform these low risk waived tests.

There are more than 120 CLIA-waived analytes that can be used for acute and chronic diseases. Common examples include:

- Hemoglobin A1c
- Blood glucose
- Albumin
- Influenza

- Group A Streptococcus
- Hepatitis C
- Human Immunodeficiency Virus

For a comprehensive list of CLIA-waived tests, the FDA provides pharmacists a valuable resource online at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm. Additional information can be found by contacting the purchasing vendor of a particular test.

What is a CLIA laboratory?

Under CLIA, a laboratory is defined as a facility that performs testing 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 assessment of the health of, human beings. A pharmacy offering CLIA-waived would qualify as a laboratory. In fact, 18% of pharmacies nationwide -- more than 10,800 pharmacies -- currently serve as CLIA-waived laboratories.

Each laboratory must have a qualified "laboratory director." CMS defines a laboratory director as the administrator of the laboratory who demonstrates active involvement in the laboratory operation and employment of qualified personnel. It is the responsibility of the laboratory director to implement and maintain a quality assurance system in order to achieve accurate and reliable patient test results. There are no explicit education, experience, or training requirements to become a laboratory director of a site performing only CLIA waived testing -- though it is an expectation that the facility list a laboratory director with proper credentials. A pharmacist or pharmacy technician with appropriate training may be the registered laboratory director of an unlimited number of sites.

How to Obtain a Certificate of Waiver (CoW)

In order to register your pharmacy and obtain a CoW to begin performing waived testing, the laboratory director must submit the following:

- Federal CMS 116 laboratory registration form (submit to Idaho Bureau of Laboratories) https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS116.pdf

Of note, a CoW is needed for each pharmacy before performing testing, unless you qualify under an exception below:

- Laboratories that are not at a fixed location, that is, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the certificate of the designated primary site or home base using its address.
- Not-for-profit or Federal, State or local government laboratories that

engage in limited public health testing may file a single application.

- Laboratories within a hospital that are located at adjoining buildings on the same campus and under common direction may file a single application for the laboratory sites within the same physical location or street address.

The following instructions are a brief synopsis -- adopted from the CDC -- of what type of information is needed when using a Form CMS-116:

I. General Information – provide information about your organization, including street address, name of director, and federal tax identification number. Don't fill out the CLIA identification number if this is an initial application.
II. Type of Certificate Requested – request a Certificate of Waiver.
III. Type of Laboratory – indicate the facility or setting in which you will perform the test, e.g., #20 Pharmacy
IV. Hours of Laboratory Testing – indicate the times you plan to do testing.
V. Multiple Sites – indicate if you will be doing testing at more than one site.
VI. Waived Testing – estimate the number of tests you will be performing annually.
VII. Provider Performed Microscopy Testing – skip this section if you are performing a waived test only.
VIII. Non-Waived Tests – skip this section if you are performing a waived test only.
IX. Type of Control – check the type of organization for which you are making this application (private non-profit, for-profit, government).
X. Director Affiliation With Other Laboratories – provide the name and address of other laboratories (pharmacies) that your director also directs.
XI. Consent and Signature – carefully read the consent information at the bottom of p. 4 before signing and dating.

What if information provided on my application changes?

If your pharmacy experiences a change in ownership, name, address, or director; you must notify the IBL Laboratory Improvement Section of these changes within 30 days. You can reach their office to update your CoW at (208) 334-0528, or email labimprovement@dhw.idaho.gov.

What does the CLIA certification cost?

The online registration to comply with state law regarding registration of clinical labs with the Idaho Bureau of Labs, at this time, is free of charge. After applying for your CoW, you will receive a federal fee coupon assessing a $150 fee payable to CMS.

When can I start testing?

The Idaho Bureau of Labs will typically process your CoW request within 5-7 business days. Once your application is approved, you will receive an electronic letter with a state identification number and a federal CLIA number. Upon receiving this letter you may begin waived testing. Your federal fee coupon will arrive within two weeks after the Idaho Bureau of Labs processing of your application. Once the fee is received by CMS, your certificate of waiver will be mailed to

you. A note to remember, most billing claims for laboratory services must include the CLIA number for the laboratory.

When do I need to renew my certificate of waiver?
An approved certificate of waiver is valid for two (2) years. In order to keep a valid CoW; a biennial state and federal renewal form must be submitted to the Idaho Bureau of Labs, and a $150 renewal payment must be submitted to CMS. Your pharmacy will receive a bill directly from CMS within six to twelve months before your certificate expires, as a reminder to renew your CoW.

Do we need to notify anyone if we are adding/removing waived tests that our pharmacy provides?
The Idaho Bureau of Labs and CMS do not require notification of the addition or removal of specific tests provided at your pharmacy, as long as all provided testing is still considered waived tests.

Administering Waived Tests
There are no minimum training requirements specified in federal or state law for the personnel conducting waived tests. Both pharmacists or pharmacy technicians may participate in administering waived testing, though they should only provide those for which they have proper education and training.

Under CLIA, to administer a waived test, you must follow the manufacturer's' instructions for the waived test being performed. This means that personnel should follow all of the instructions in the most current product insert from “intended use” to “limitations of the procedure.” Following the quick reference instructions guidelines is not a valid method of administering tests, and can yield inaccurate results.

When performing the test, CMS recommends administrators to:

- Observing storage and handling requirements for the test system components;
- Adhering to the expiration date of the test system and reagents, as applicable;
- Performing quality control, as required by the manufacturer;
- Performing function checks and maintenance of equipment;
- Training testing personnel in the performance of the test, if required by the manufacturer;
- Reporting patients’ test results in the units described in the package insert;
- Sending specimens for confirmatory tests, when required by the manufacturer; and
- Ensuring that any test system limitations are observed.

The CDC has published step by step guidelines on how to administer waived tests and what to consider online at http://wwwn.cdc.gov/clia/Resources/WaivedTests/. Resources provided include:

- Ready? Set? Test! Booklet and Online course
- To Test or Not to Test? Booklet
- MMWR R&R Good Laboratory Practices for Waived Testing Sites

Properly Documenting Administered Tests

Under CLIA, a record of laboratory test results are required to be maintained for two (2) years; all pharmacy records in Idaho should be kept for three (3) years, however. Laboratories are also required to include the data, quality control, and proficiency testing relating to the performed waived tests.

Do I need to report my results to any entity?

While not a specific federal or state requirement, pharmacists should collaborate closely with the patient's primary care provider with respect to test results to ensure collaborative, team-based care.

In addition, Idaho maintains a Reportable Disease List. Health care providers, laboratorians, and hospital administrators are required, according to the Rules and Regulations Governing Idaho Reportable Diseases (IDAPA 16.02.10), to report the certain communicable diseases -- such as Hepatitis C or HIV -- to their local health district or Bureau of Communicable Disease Prevention (BCDP). A comprehensive listing of reportable diseases follows: http://healthandwelfare.idaho.gov/portals/0/Health/MoreInformation/ReportableDiseasePoster04302008.pdf.

Is my pharmacy subject to inspection?

Routine inspections of CoW laboratories are not required. If a formal complaint is made, the IBL will inform your laboratory director of the alleged information and notify if an upcoming inspection will occur. The CLIA program does perform educational visits to a small number CoW labs each year to help answer questions and encourage good lab practice. These visits occur at approximately 1-2% of CoW laboratories performing waived tests per year.

References:

1. Centers for Medicare and Medicaid Services https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html. Accessed June 14, 2016.
2. U.S. Food and Drug Administration http://www.fda.gov/medicaldevices/deviceregulationandguidance/ivdregulatoryassistance/ucm124105.htm. Accessed June 14, 2016
3. Centers for Disease Control and Prevention http://wwwn.cdc.gov/CLIA/Default.aspx. Accessed June 14, 2016
4. Idaho Bureau of Laboratories http://healthandwelfare.idaho.gov/Health/Labs/LabandXRayCertification/tabid/186/Default.aspx. Accessed June 14, 2016.

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