**DEPARTMENT OF HEALTH & HUMAN SERVICES** Centers for Medicare & Medicaid Services

7500 Security Boulevard
Baltimore, MD 21244-1850

SMDL # 02-004

April 1, 2002

Dear State Medicaid Director:

The Centers for Medicare & Medicaid Services (CMS) is initiating on-site visits to facilities enrolled in the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program that have a certificate of waiver (COW). The CLIA program conducted an initial pilot study in the States of Colorado and Ohio, where on-site visits of a random sample of 200 CLIA COW and certificate of Provider Performed Microscopy Procedures (PPMP) laboratories were performed. Significant quality and certification problems were identified in over 50 percent of these laboratories.

CMS expanded this pilot to include eight additional States to verify the scope and seriousness of Colorado's and Ohio's initial study findings. As a result of this expanded pilot, quality problems were identified that corroborated the initial study findings, which included:

- 32 percent failed to have current manufacturer's instructions;
- 32 percent didn't perform quality control as required by manufacturer or Centers for Disease Control and Prevention (CDC);
- 16 percent failed to follow current manufacturer's instructions;

The Centers for Disease Control and Prevention (CDC), Office of Inspector General (OIG) and New York studies have similar findings.

Due to the significant increase in the number and types of tests waived, the rapidly expanding number of laboratories with no oversight, and the serious findings in COW laboratories, CMS will be visiting two percent of the COW laboratories starting early 2002. The laboratories will be notified in advance, first by letter and then by telephone to confirm the on-site visit. The visits will focus on the education of testing personnel to ensure quality testing. If quality problems are found, the inspectors will provide assistance to the laboratories to achieve accurate and reliable results. If certificate problems are found, the inspectors will ensure the laboratories operate under the correct certificate. There will be no fee charged to the laboratories at this time for these visits. Preliminary follow up data from CMS's expanded pilot studies indicates the educational approach to be highly effective. Other educational efforts for COW laboratories are in development.

Enclosed you will find a CMS Fact Sheet, Questions and Answers, and Surveyor Questions COW Laboratories. Please do not hesitate to contact Judith A. Yost of my staff at telephone number (410) 786-3407 or by email at jyost@CMS.HHS.gov with your questions or concerns.

Sincerely,

/S/

Dennis G. Smith
Director
Center for Medicaid and State Operations

Enclosures

cc:

CMS Regional Administrators

CMS Associate Regional Administrators
for Medicaid and State Operations

Lee Partridge
Director, Health Policy Unit
American Public Human Services Association

Joy Wilson
Director, Health Committee
National Conference of State Legislatures

Matt Salo
Director of Health Legislation
National Governors Association

Brent Ewig
Senior Director, Access Policy
Association of State and Territorial Health Officials

Jennifer King
Director, Health and Human Services Task Force
American Legislative Exchange Council

Trudi Matthews
Senior Health Policy Analyst
Council of State Governments

**CMS FACT SHEET**

Visiting CLIA
Certificate of Waiver Laboratories

## BACKGROUND

Congress passed the Clinical Laboratory Improvement Amendment s(CLIA) in 1988. CLIA requires all laboratories that examine materials derived from the human body for diagnosis, prevention, or treatment purposes to be certified by the Secretary of Health and Human Services. The Centers for Medicare & Medicaid Services (CMS) (formerly the Health Care Financing Administration) operates the CLIA laboratory certification program for the Secretary in conjunction with the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA).

For many Americans, the accuracy of clinical laboratory test results can be a life or death matter. For instance, if a clinical laboratory misreads a patient's blood sample as having a normal cholesterol level, when in fact it is high in cholesterol, that patient may not receive the treatment needed to prevent a heart attack. It is also important to note that even though waived tests are deemed simple to perform, erroneous results are possible and can produce untoward patient outcomes if acted upon. For example, glucose tests performed on a meter approved by FDA for home use are waived under CLIA and can be done at any site by any person. Thus, in a point of care setting such as a skilled nursing facility (SNF), these test results can be utilized to monitor a patient's treatment to determine their next dose of insulin. If the SNF does not train its testing personnel to follow the manufacturer's instructions, to control and maintain the device appropriately, and to read the test results within the specified time frame, a patient could receive an incorrect insulin dose and sustain potentially dangerous consequences.

## Waived Tests and Facilities

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

The COW laboratories must meet only the following requirements under CLIA:

- Enroll in the CLIA program;
- Pay applicable certificate fees biennially; and
- Follow manufacturers' test instructions.

The number and types of tests waived under CLIA has increased from 8 tests to 40 since the inception of the program in 1992; thereby, the number of COW laboratories has grown exponentially from 20 percent to 55 percent of the total 174,504 laboratories enrolled.

The regulations, however, do provide for oversight of COW laboratories under certain circumstances such as:

- If a complaint is alleged;
- To determine if a laboratory is testing beyond the scope of its certificate;
- If there is risk of harm due to inaccurate testing; and,
- To collect information about waived tests.

**Initial Pilot Study**

Due to the increases in the types of tests waived, the large number of laboratories with no oversight, and the serious findings in complaint investigations of these waived laboratories, the States of Colorado and Ohio initiated on-site inspections of a random sample of 200 CLIA COW and Provider Performed Microscopy Procedures (PPM) laboratories. These pilots consisted of focused on-site inspections with prior notification and screening of the laboratory to confirm whether the State's concerns about quality problems were correct. Significant quality and certification problems were identified in over 50 percent of these laboratories. If quality problems were found, the inspectors provided assistance to the laboratories to achieve accurate results. Ohio found 10 percent and Colorado found 7 percent of the laboratories inspected to be testing beyond their certificates. These laboratories were performing moderate complexity tests and, if properly enrolled in CLIA, would be subject to biennial inspections and additional fees.

**Expansion of Pilot Study**

To verify the scope and seriousness of these initial findings, CMS expanded this pilot to include 8 additional States. Using Colorado and Ohio's pilot as a model, CMS visited 2.5 percent (approximately 460) of COW and PPMP laboratories in 8 selected States. The visits were conducted with an educational approach. CMS believes it is obligated to follow up on these major findings as an effective steward of quality and to be responsive to the public good.

**Results of Expanded Pilot Study**

Quality problems were identified in these laboratories which included:

- 32 percent failed to have current manufacturer's instructions;
- 32 percent didn't perform quality control as required by manufacturer or CDC; and,
- 16 percent failed to follow current manufacturer's instructions.
- The Centers for Disease Control and Prevention, Office of Inspector General, and New York studies have similar findings.

**Next Steps**

Starting in early 2002 CMS will be initiating on-site visits to approximately 2 percent of COW laboratories as a result of the significant quality findings in the above mentioned studies. These visits will continue to be information-gathering and educational. Preliminary follow-up data from the expanded pilot study indicates that the education provided during these on-site visits is effective. Additionally, CMS is compiling information about existing COW laboratory education programs and vehicles. By working together with our partners and stakeholders we will ensure that every COW laboratory can ultimately receive education about basic good laboratory practices and how to understand and follow manufacturer's instructions.

# QUESTIONS AND ANSWERS FOR ON SITE VISITS OF CLIA CERTIFICATE OF WAIVER LABORATORIES

1. **What is "CLIA"?**

   "CLIA" is the acronym for the Clinical Laboratory Improvement Amendments of 1988. This law requires any facility performing examinations of human specimens (e.g., tissue, blood, urine, etc.) for diagnosis, prevention, or treatment purposes to be certified by the Secretary of the Department of Health and Human Services.

2. **Why is CLIA important?**

   For many Americans, the accuracy of clinical laboratory test results can be a life or death matter. If glucose tests are not performed correctly, a patient could receive an incorrect insulin dose and sustain potentially dangerous consequences. If your cholesterol is high and the laboratory results are reported as normal, you may not receive the care necessary to prevent a heart attack.

3. **What is waived testing?**

   By the CLIA law, waived tests are those tests that are determined by CDC or FDA to be so simple that there is little risk of error. Some testing methods for glucose and cholesterol are waived along with pregnancy tests, fecal occult blood tests, some urine tests, etc. Currently, 40 tests have been approved for certificate of waiver (COW) status at CLIA website http://www.fda.gov/cdrh/clia.

4. **What does CLIA require of a COW laboratory?**

   COW laboratories must enroll in the CLIA program, pay applicable certificate fees biennially, and follow manufacturers' test instructions.

5. **How many laboratories hold a COW?**

   Of the 174,504 laboratories enrolled in CLIA, approximately 93,129 (55%) of these hold a COW.

6. **Why is CMS visiting COW laboratories on site?**

   Colorado and Ohio performed on-site inspections of a random sample of 200 CLIA COW and Provider Performed Microscopy Procedures (PPMP) laboratories. Significant quality and certification problems were identified in over 50 percent of these laboratories. CMS expanded the initial pilot to include 8 additional States across

the nation, verifying the scope and seriousness of Colorado's and Ohio's initial findings and other studies. Quality problems were identified in those laboratories. Therefore, CMS is initiating on-site visits to facilities enrolled in CLIA that have COW certificates.

**7. What types of COW laboratories will CMS visit?**

CMS will visit all laboratory types, such as community clinics, HMOs, skilled nursing facilities, rural health clinics, physician office laboratories, etc. The number of each facility type visited will reflect the overall percentage of each type in our database.

**8. How many COW laboratories will CMS visit?**

CMS will be visiting 2 percent of COW laboratories within the United States annually.

**9. Since the COW laboratories are not routinely inspected, how will CMS approach these laboratories?**

CMS believes an educational approach is necessary for these laboratories. Inspectors will focus on the education of testing personnel to ensure quality testing. If quality problems are found, the inspectors will provide assistance to the laboratories to achieve accurate and reliable results. If certificate problems are found, the inspectors will ensure the laboratories operate under the correct certificate.

**10. Has the educational approach been effective?**

Yes, preliminary data from follow-up visits indicate education has been effective. Laboratories are continuing with the practices they learned.

**11. What was the reaction to the educational surveys in the expanded pilot?**

Each COW facility in the expanded pilot was given a discreet, anonymous evaluation to rate their experience during the on-site visit. Seventy-five percent responded that the educational visit was overall good and useful. One POL director, a MD, stated that any effort to improve testing in POLs is welcome.

**12. How will CMS notify the COW laboratories that have been selected?**

COW laboratories will be notified in advance, first by letter and then by telephone to confirm the on-site visits.

**13. Will CMS assess a fee for these on-site visits?**

No fee will be assessed for these visits.

**14. What else is CMS doing to assure quality testing in COW laboratories?**

CMS is working with their partners and stakeholders to develop and ensure comprehensive educational programs through various mechanisms are available and provided to COW laboratories. CMS will also include educational information on its CLIA website at www.hcfa.gov/medicaid/clia/cliahome.htm

Additionally, CMS will work with manufacturers to provide initial training to testing personnel and provide clear instructions with the test system.

**15. What if education doesn't work?**

CMS in conjunction with Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA) will evaluate other alternatives for ensuring quality.

**16. Will COW laboratories close because of these visits?**

The number of COW laboratories has steadily increased over time. In 1992, it was estimated 20% of laboratories would be COW. In 2002, 54 percent are COW. Responses on the survey evaluation form called the visits a good idea, and valuable for assuring good performance. Well-performed waived testing is an important tool for patient care and is supported by CMS. It will continue to be used in a variety of settings.

Internal Q and A
Questions

1. **Do we have information concerning adverse outcome as a result of inaccurate waived testing?**

Yes, we have some anecdotal information. For example: A Medical Technologist in Alabama is the mother of 4 diabetic sons. Each morning all sons are tested for glucose before breakfast. One son's result was flagged with an error code. Because this was a new instrument and the mother wanted to verify the accuracy of the test, the mother took that son to the doctor's office. The POL performed the glucose test using a waived glucose instrument. The results were normal; despite the clinical symptoms presented by the son. No intervention was recommended by the doctor's office. The mother was still concerned and doubted the results. She took her son to the hospital emergency room to have the glucose confirmed on a non-waived instrument (moderate complexity test). The ER results showed an elevated blood sugar and appropriate treatment was rendered. Because this mom had laboratory background, she was able to discern that something was amiss. If she had not questioned the POL's waived instrument results, preventable harm could have resulted. Another example involves the use of test cards detecting fecal occult blood. Some waived laboratories were found to be cutting the test cards in halves or thirds in order to save money. The cards have predetermined amounts of reagent and cutting them alters the chemical distribution. This will affect the patients' test results. False negative could result in delay of diagnosis/treatment for colorectal cancer.

2. **Does testing have to be as accurate as that performed in other laboratories since the physician is available to correlate the test results and the patient's history and symptoms?**

The CLIAC notes of the May 30-31, 2001 meeting state "…waived tests should have higher accuracy standards than moderate or high complexity tests." The importance of performing the tests properly to avoid adverse outcomes cannot be emphasized enough. All test results must be accurate and reliable in order to properly diagnose and treat patients regardless of where performed. Test results must be accurate and reliable because all patients may not present with classic symptoms or may have numerous physiological problems. In the aforementioned example, the inaccurate POL glucose test meant the patient did not receive appropriate treatment immediately and could have caused harm or death to the patient. Also tests in waived laboratories need to be accurate because there are no other mechanisms like quality control, testing personnel qualifications and training, quality assurance, etc. to ensure that there are accurate results and problems are identified and resolved. The CLIAC notes of the May 30-31, 2001 meeting state further, "A physician member noted accurate prothrombin time results are critical in an emergency room and using test results from a home-use device, which can be inaccurate, could lead to unnecessary transfusions or inappropriate anticoagulant treatment," and, "Many Committee members noted these monitoring devices, designed for self-use by lay-users, are inappropriately used as diagnostic tools by health care providers." Waived tests designed for screening are being used for diagnosis and

treatment. The adverse outcome of a waived test result used inappropriately (for diagnosis rather than screening), or of an inaccurate waived test is not always apparent at the POL or waived facility. ASPE, using Medicare data, did a study involving prothrombin times done in doctor's offices (waived tests) compared to those done in surveyed laboratories (moderate or high complexity tests). Many more re-admissions to hospitals and additional testing occurred with the patients seen in the POLs compared to the surveyed labs. In addition, a study was published in the early 1990's about multiple deaths that occurred in nursing homes due to inaccurate glucose meter testing.

**SURVEYOR QUESTIONS**
**CERTIFICATE OF WAIVER LABORATORIES**

**Laboratory:** **COW since what date:**

**CLIA #** **State:** **State Laboratory Licensure Program: Y or N**

**Surveyor:** **Date:**

**Estimated annual test volume:** **Number of different tests:**

PLEASE ANSWER **EVERY** QUESTION.

| | YES | NO | N A | COMMENTS |
|---|---|---|---|---|
| 1. Are all tests performed classified as waived? **493.15(c) and 493.1775(b)(3)** | | | | See the attached list. |
| 2. If the answer to #1 is NO, list the non-waived tests. **493.1775(b)(3)** | | | | |
| 3. Does the laboratory operate in and perform testing in a manner that constitutes an imminent and serious risk to public health? If the answer is YES, contact the RO for further instructions (ASAP). **493.1775(b)(1)** | | | | |
| 4. Does the laboratory **have** the current manufacturer's instructions for the tests performed? **493.15(e)(1)** | | | | |
| 5. Does the laboratory **follow** the current manufacturer's instructions for the tests performed by: **493.15(e)(1)**<br>a) Using the appropriate specimen? | | | | |
| b) Adding the required reagents in the prescribed order? | | | | |
| c) Adhering to the manufacturer's storage and handling instructions? | | | | |
| d) Using the proper expiration date for the storage method? | | | | |
| e) Performing the quality control? | | | | |
| f) Performing additional requirements defined by the CDC? | | | | |
| g) Performing function checks or calibration? | | | | |
| h) Performing confirmatory tests as required? | | | | |
| i) Reporting the patients' test results with the terminology or in the units described in the package insert? | | | | |

| | YES | NO | NA | COMMENTS |
|---|---|---|---|---|
| j) Performing instrument maintenance? | | | | |
| 6. Are there problems with the manufacturer's instructions? E.g. unclear or complex language, etc. Send copies of problem package inserts to CO. | | | | |
| 7. Are the testing personnel instructed to:<br>a) Retain the current manufacturer's product insert? | | | | |
| b) Read and follow the manufacturer's instructions in the product insert? | | | | |
| c) Document the name of the test, lot number, and expiration date? | | | | |
| 8. Is there training for the testing personnel? (Please note **who** provided the training).<br><br>a) Is the staff observed or evaluated to assure they can provide accurate and reliable testing? | | | | |
| b) Are the testing personnel shown how to document the patient's test results? | | | | |
| c) Are the testing personnel shown how to identify inaccurate results and/or test system or device problems? | | | | |
| d) Are the testing personnel shown how to handle inaccurate results or device problems? | | | | |
| e) If training courses were developed for waived laboratories, would you attend? If NO, why not? | | | | |
| f) What type of training would you find helpful? (Please describe). | | | | |
| 9. Are the testing personnel informed when there's a change in the test procedure or there's a new test kit? (If NO, note how the testing personnel learned about the new test).<br>a) If YES, is training given? (Please note **who** provided the training). | | | | |
| b) Has there been a change in (new) testing personnel within the last 12 months? | | | | |
| c) Is the laboratory informed when there is a revision to the manufacturer's product insert? | | | | |
| d) Are the products clearly labeled to advise of a revision? | | | | |

| | YES | NO | N A | COMMENTS |
|---|---|---|---|---|
| 10. Have the testing personnel ever been asked to repeat a waived test?<br>a) If YES, was the second result different than the original result? | | | | |
| b) If YES, what result was used by the physician? | | | | |
| c) If No, was action taken to resolve the differences? | | | | |
| 11. Does the laboratory have an understanding of good laboratory practices? | | | | |
| a) Are patient results correlated with patient information? | | | | |
| 12. Does the laboratory :<br>a) Check patient identification? | | | | |
| b) Collect the proper specimen for the test requested? | | | | |
| c) Require a requisition (or patient's chart) before performing a test? | | | | |
| d) Maintain a log or record of laboratory tests performed? | | | | |
| e) Keep the patient's test report in the patient's chart? | | | | |
| f) Keep the reference laboratory results in the patient's chart? | | | | |
| 13. Does the laboratory use any waived test kits that require additional confirmatory procedures? (Some rapid strep kits may recommend or require a throat culture if the patient's test result is negative).<br>a) If YES, does the laboratory meet the additional requirements defined by CDC or the manufacturer? (Please write the name of the test and send CO a copy of the package insert). | | | | |
| b) If YES, are the testing personnel trained to perform the additional requirements? | | | | |
| c) If YES, is the laboratory sending out the specimen to meet the additional requirement? | | | | |
| d) If the specimen is sent out to meet the additional requirements, does the laboratory report results prior to receiving the confirmation report? | | | | |
| e) Are the results of the confirmatory test documented? | | | | |

| | YES | NO | N A | COMMENTS |
|---|---|---|---|---|
| 14. Is the laboratory performing diagnostic glucose testing? (e.g., GTT, 2 hour post-prandial, diagnosis of diabetes, diagnosis of gestational diabetes). If YES, please write the name of the instrument and send CO a copy of the package insert. | | | | |
| 15. If the laboratory performs glucose, prothrombin, or any quantitative analyte waived testing, what does the laboratory do when the results are outside the reportable range of the instrument?<br>a) Repeat the test. | | | | |
| b) Notify the physician. | | | | |
| c) Draw blood and send it to a reference laboratory. | | | | |
| d) Send the patient to the hospital. | | | | |
| e) Other (please describe) | | | | |
| 16. Does the laboratory identify questionable or erroneous test results for waived tests? | | | | |
| a) Instrument or device error codes | | | | |
| b) Internal (procedural) quality control failure | | | | |
| c) External (liquid) quality control failure | | | | |
| d) Electronic quality control failure | | | | |
| e) Proficiency testing failure | | | | |
| f) Test results don't match patient's symptoms or history | | | | |
| g) Other (please describe) | | | | |
| h) The laboratory **cannot identify** erroneous or questionable results for waived tests. | | | | |
| 17. Are the laboratory's results timely? | | | | |
| 18. Is the laboratory voluntarily enrolled in proficiency testing? | | | | |
| 19. Has the lab ever received a complaint that involved waived testing? If YES,<br>a) Who submitted the complaint? | | | | |
| b) Did the laboratory investigate the complaint? | | | | |
| c) Does the laboratory have a mechanism for handling complaints? | | | | |
| d) Does the laboratory get repeat complaints? | | | | |
| e) Is there someone assigned to investigate complaints? (Please indicate the complaint investigator). | | | | |

| | YES | NO | N A | COMMENTS |
|---|---|---|---|---|
| 20. Has the laboratory had another CLIA certificate prior to the current Certificate of Waiver? If YES: | | | | |
| a) Indicate what type in the comment box. | | | | |
| b) Did the laboratory change certificate type as a plan of correction? | | | | |
| c) Did the laboratory have condition level deficiencies on the inspection? | | | | |
| 21. Did you give the laboratory the 668B? | | | | |
| **Testing Personnel**<br>**Please check all that apply.**<br>Dentist<br>Physician (M.D., D.O.)<br>Podiatrist (D.P.M.)<br>Physician's Assistant<br>Registered Nurse (R.N.)<br>Nurse Practitioner<br>Licensed Practical Nurse (LPN)<br>Medical Technologist (B.S.)<br>Medical Laboratory Technician<br>MLT (A.A. )<br>Medical Assistant<br>Military Training<br>High School Diploma<br>Other (please specify) | | | | |
| **Laboratory Director:**<br>Dentist<br>Physician (M.D., D.O.)<br>Podiatrist (D.P.M.)<br>Physician's Assistant<br>Registered Nurse (R.N.)<br>Nurse Practitioner<br>Licensed Practical Nurse (LPN)<br>Medical Technologist (B.S.)<br>Medical Laboratory Technician<br>MLT (A.A. )<br>Medical Assistant<br>Military Training<br>High School Diploma<br>Other (please specify) | | | | |

| | YES | NO | N A | COMMENTS |
|---|---|---|---|---|
| Name the tests you would still perform if these tests were **not** waived. | | | | |

| **Use this space to describe any situations where waived testing caused a problem with a patient (list the type of testing, inaccurate results, etc).** |
|---|
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |

SURVEY TIME

Pre-survey:

On-site:

Travel:

*Post-survey:

*The post survey time does not include the final report for RO and CO.

Final Jan. 31, 2002