

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 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.