CMS FACT SHEET

Visiting CLIA
Certificate of Waiver Laboratories

BACKGROUND

Congress passed the Clinical Laboratory Improvement Amendments (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.