What You Need to Know About Waived Testing & Competency Assessment for Non-waived Testing
Objectives

• General overview of CLIA

• Guidance on regulations regarding waived testing

• Guidance on regulations regarding competency assessment for non-waived testing
What is “CLIA”? 

• Clinical Laboratory Improvement Amendments

• Federal program that establishes quality laboratory standards to protect patient safety and improve health care
CLIA Program Responsibilities

CMS
Clinical Laboratory Oversight

CDC
Scientific Consultation

FDA
Test Categorization
The CLIA regulations.....

- Established uniform quality standards for all laboratory testing to ensure accuracy, reliability and timeliness of patient test results regardless of where the test was performed.
CLIA Definition of Laboratory

- Any facility that examines human specimens for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings
All clinical laboratories....

- that perform testing on patient specimens must:
  - apply for a CLIA certificate
  - pay appropriate fees and
  - follow applicable CLIA requirements
Test Complexity

• Waived
• Moderate complexity including the subcategory of Provider Performed Microscopy (PPM)
• High complexity

Laboratories are certified at the highest level of testing performed
CLIA Certificate Types

• Certificate of Compliance (COC)
• Certificate of Accreditation (COA)
• Certificate for PPM procedures (PPMP)
• Certificate of Waiver (CoW)
Current Enrollment Statistics

- Total Number of Laboratories: 244,564
  - Compliance Labs: 18,959
  - Accredited Labs: 16,081
  - Waived Labs: 165,058
  - PPM Labs: 36,784
Waived Tests....

- Simple laboratory examinations and procedures
- Cleared by 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.
Certificate of Waiver (CoW)

• Enroll in the CLIA program
• Pay biennial certificate fees
• Only perform tests categorized as waived
• Not subject to routine inspections
• Must follow manufacturer’s instructions
CoW Personnel Requirements

• Must have a Laboratory Director
  o There are no educational and experiential requirements for LD

• There are no other personnel requirements
CoW Site Visits

• Announced, designed to help educate on sound laboratory practices

• Surveyors determine:
  o Testing being conducted in manner that protects patient safety
  o Regulatory compliance
  o Performing tests appropriate for a CoW lab
CDC Educational Materials

- CDC has published “Ready, Set, Test” booklet - describes recommended practices for physicians, nurses, medical assistants and others performing patient testing under a CLIA Waiver Certificate.

- CDC also offers an on-line training course corresponding to “Ready, Set, Test”.

CLIA
Good Laboratory Practices for Waived Testing Sites

Poster and postcards

Educational booklet with job aids
Non-waived Testing

- Includes moderate and high complexity tests
- Must follow:
  - All manufacturer’s instructions and
  - Applicable CLIA requirements
  - AO requirements
  - State requirements (ex. Maryland, New York)

When in doubt, always follow the most stringent requirements
New FDA BGM Limitation

- FDA required limitation in manufacturer’s BGM instructions/pkg inserts that prohibit use of meter for critically ill patients.

- CMS only recently made aware of this limitation being placed in instructions/inserts.
What does this limitation mean?

- Devices used outside of the manufacturer’s requirements are considered to be test modification/off label use.
- This is not a new CLIA regulation!
Test modification/off label use

• Any change to a test system/device or manufacturer’s instructions or intended use that affects the test’s performance specifications for accuracy, precision, sensitivity or specificity.

• Modified tests become high complexity tests under CLIA
If using meters with the “critically ill” limitation:

- Define “critically ill” for their specific patient populations
- Establish performance specifications (42 CFR § 493.1253)
If using meters with the “critically ill” limitation

- Obtain a CLIA Certificate of Compliance (COC) or Certificate of Accreditation (COA), pay applicable fees
- Meet all other high-complexity requirements (ex. Proficiency Testing, Personnel requirements)
Definition of “Critically Ill”

• Due to myriad of factors, circumstances and patient populations, it is up to each laboratory/facility to define “critically ill” for its specific patient populations.

• FDA and CMS will not define “Critically Ill”
Other Laboratory Options

- Use POC test systems without the “critically ill” limitation
- Send glucose tests to main laboratory
  - Presents patient care issues due to volume of blood required, need for frequent testing
Performance Specification

Resources

- 42 CFR § 493.1253 of the CLIA Interpretive Guidelines (IG)
- CLIA Brochure #2, “Verification of Performance Specifications” on the CLIA/CMS website
  - www.cms.hhs.gov/CLIA
CLIA Personnel & Competency Policies

Topics for Discussion

- CLIA Personnel Policies
- Rationale for Policies
  - Outcomes
  - Goal of Discussion
- Competency Assessment
High Complexity Personnel

- Laboratory director (LD)
- Technical Supervisor (TS)
- Clinical Consultant (CC)
- General Supervisor (GS)
- Testing Personnel (TP)
Moderate Complexity Personnel

• Laboratory director (LD)
• Clinical consultant (CC)
• Technical consultant (TC)
• Testing personnel (TP)
CLIA Personnel Policies

• Use CMS Interpretive Guidelines (IG) & S & C Letter 10-07-07-CLIA as a guide

• Qualification evaluations are done at the highest level of academic achievement for the position.
CLIA Personnel Policies

- All required positions & a sample of TP are reviewed once.
  - Review add’l. TP on subsequent surveys along w/ any changes or new personnel
  - If a LD changes, quals. are reviewed by the appropriate AO/SA upon notification prior to approval.
- LD responsibilities correspond to all quality standards
CLIA Personnel Policies

- Phlebotomists, micro plating personnel, clerks, reagent & specimen prep, etc. who do not test are NOT reviewed.
- MT(ASCP) & nursing licenses alone aren’t acceptable.
- Even if certification is required by CLIA; e.g., CT, degrees & transcripts, etc. are still required.
- If a State license is required by CLIA, it alone is acceptable. Most States do an extensive review.
- Surveyor may still request documentation.
CLIA Personnel Policies

• Consider test complexity when evaluating credentials.

• Agency evaluations aren’t acceptable, except for foreign credentialing equivalency purposes.

• Foreign educated individuals must be evaluated by a nationally recognized agency for equivalency.
CLIA Personnel Policies

• If an individual doesn’t meet education, training or experience requirements, position not filled or responsibilities not met, a condition level deficiency is cited.

• Competency is assessed per the regulations for TC/TS.

• Solo practitioners are not assessed.
CLIA Personnel Policies: Rationale

• Individuals download qualifications from the Web, use fraudulently to obtain CLIA certificates, and bill Medicare for millions of $$.

• More than 100 false applications recorded so far. Many shell labs caught by pre-approval review of application credentials.

• ASCP has changed its credentialing process after discovering individuals who submitted false credentials for their certification.
CLIA Personnel Policies: Rationale

- There is great risk to CLIA & patients if an individual in a regulated position is ID’d as unqualified & quality issues are also found.

- Lab w/ multiple, consecutive PT failures had TP w/ falsified HEW card. All lab results had to be reviewed.
CLIA Personnel Policies: Rationale

- Offshore operation upgrades degrees for a fee; diploma mills; quickie degrees.
- TP (with only 10th grade education) not following mfgr’s. instructions for intended use (endocervical) - testing males for GC/Chlamydia
- Lab w/ all personnel unqualified for high complexity micro testing it performed.
CLIA Personnel Policies: Rationale

- **Immediate Jeopardy** found in lab where GS had no foreign equivalency done.

- TP w/ no HS degree or GED – test results impacted.

- POL w/ repeated deficiencies – MD’s high school age son performing testing.
CLIA Personnel Policies - Goals

1. All oversight agencies have and enforce consistent personnel policies.

2. Patients are protected by qualified personnel at all levels.
CLIA Competency Assessment

- Competency is required for all technical, supervisory & testing personnel (TP).
- Requires 6 elements for all tests for TP.
- Various related requirements are interspersed throughout the regulations.
CLIA Competency Assessment

• Competency is NOT the same as a performance evaluation/training.

• Quality management includes personnel, processes, & procedures, as does competency.
CLIA Competency Assessment

• Studies indicate that more education & training produce higher quality results.

• The means to confirm training effectiveness is competency evaluation.

• In CLIA, laboratory director’s qualifications are stringent due to overall quality responsibility.

• But qualifications for testing personnel are minimal, based on test complexity.
CLIA Competency Assessment

• CLIA survey experience indicates many problems caused by personnel errors which may have a patient impact.

• Routine competency evaluations help prevent errors; highlight importance of competency, regardless of education.
CLIA Competency Assessment: Key Requirement

Technical Consultant/Supervisor Responsibilities

(§493.1413(b)(8)(9) and §493.1451(b)(8)(9))

- Evaluating the competency of all testing personnel & assuring that the staff maintain their competency to perform test procedures & report test results promptly, accurately, & proficiently
CLIA Competency Assessment

Must Include:

1. Direct observation of routine patient test performance, including patient preparation, if applicable, specimen handling, processing & testing.

2. Monitoring the recording & reporting of test results
**CLIA Competency Assessment**

**Must Include:**

3. Review of intermediate test results or worksheets, QC records, PT results, & preventive maintenance records

4. Direct observation of performance of instrument maintenance & function checks
CLIA Competency Assessment

Must Include:

5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external PT samples; and

6. Assessment of problem solving skills
Competency Assessment Tips

• Operator training prior to testing is critical & required
• Competency assessments must be documented
• Individual conducting competency assessments must be qualified (TS/GS or TC)
Competency Assessment Tips

- **Competency assessment is not PT!**
- PT can be used to meet some elements of competency, but not all!
- Pathologists should be evaluated by the laboratory director as technical supervisors.
Competency Assessment Tips

• Competency records should match the laboratory’s actual procedures performed by its personnel.

• When observing test performance, use the procedure manual (PM) / package insert (PI) to ensure PM is current.

• Competency for clinical & technical consultants & supervisors is based on their regulatory responsibilities.
Competency Assessment Tips

• Laboratory director is not subject to competency requirements, but is accountable. Responsibilities checked on surveys.

• Do not have to do all at one time; can combine elements.

• Can often combine analytes on multichannel analyzers.
Competency Assessment Tips

- Can use competency assessment for QA when confirming tests ordered match reported/charted results.
- Follow up on QC corrective actions will demonstrate problem solving ability.
- Checklists are only minimally ok.
Competency Assessment Tips

- Competency evaluations must be done for Provider Performed Microscopy (PPM) individuals.

- Personnel performing pre & post analytic activities, but not in regulatory positions are not subject to competency, but it’s good QA.
Resources:

• CLIA Website
  o http://www.cms.gov/CLIA
  o http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm
  o http://www.cdc.gov/mmwr/pdf/rr/rr5413.pdf

• CDC: Ready, Set, Test booklet
  o http://www.cdc.gov/dls/waivedtests
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