QUICK CLIA 101 & CLIA COMPLIANCE

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Quick CLIA 101

- **Impetus for Clinical Laboratory Improvement Amendment of 1988 (CLIA):**
  - Deaths from inaccurately read Pap smears.
  - Proliferation of “blackbox” technology w/ no oversight in physicians’ offices.

Quick CLIA 101

- **Congress passed the Law in 1988.**
  - Regulates all testing on humans for health purposes using minimum quality standards.
  - To ensure accurate, reliable testing regardless of location.
  - Includes research when results returned & specimens have unique ID.

Quick CLIA 101 Cont'd.

- **Final Regulations published Feb. 1992**
  - Quality standards based on test complexity.
    - The more complex the test, the more stringent the standards.
    - Most Genetic tests are high complexity.
  - CLIA Certificate for highest test level; one per site.
    - Exceptions for hospitals/universities-multiple sites.
  - Entirely user fee funded by certificate & survey fees.
    - Based on annual test volume.
  - Program administered by CDC, FDA & CMS.

Quick CLIA 101 Cont'd.

- **Test Complexities:**
  - **Waived--** simple, accurate tests w/o routine oversight; lab must follow mfgrs.' instructions.
  - **Moderate—**most tests here; automated; lab must meet quality standards & be surveyed biennially.
  - **PPM—**provider performed microscopy-sub-category of mod.; done w/ microscope during patient visit; lab must meet quality stds.; no routine oversight.
  - **High—**manual; require more training, technique & result interpretation; most stringent stds.; surveyed.

Quick CLIA 101 Cont'd.

- **Quality Standards**:
  - **Personnel qualifications & responsibilities--**lab director has overall responsibility; required positions.
  - **Quality Control (QC)—**mechanism to ensure test is working that day.
  - **Specimen Integrity/Recordkeeping** —document test data; patient ID, confidentiality, test referral, etc.
  - **Proficiency Testing (PT)--**external test for accuracy by private org. or lab checks accuracy 2X/yr.
  - **Quality Assessment (QA)—**ongoing; system w/ comprehensive plan to monitor & ensure quality results; communicate & solve problems.

Quick CLIA 101 Cont'd.

- **CLIA Surveys**:
  - Biennial, announced.
  - Routine surveys include *only* moderate & high labs.
    - Others based on alleged complaints.
  - Performed by CMS trained State Agency Med. Techs. or
  - By approved accrediting orgs. with equivalent standards; e.g. CAP.
  - Educational, outcome-oriented with QA focus.
- Data indicates improved lab performance over time & more labs than ever enrolled in CLIA.

CLIA Compliance for G.T. Labs

GENERAL INFORMATION:

- Labs must enroll & meet all CLIA quality requirements.
- Flexibility in how & when lab meets standards.
- Priority depends on test quality impact.
- No penalties for non-enrollment; unless intentional after notification or refusal to comply.
- CMS will provide technical assistance to labs.

CLIA Compliance for G.T. Labs

SURVEY FACTS:

- First survey is information-sharing unless risk to patient safety is found.
- Survey process looks at outcomes—results.
- Problems found that affect test quality are cited on lab's survey report, but the surveyor will:
  - Offer customized guidance to correct problems,
  - Set priorities,
  - Suggest resources & timeframes for correction.
- Lab receives credit for what they do right.

CLIA Compliance for G.T. Labs

SURVEY PROCESS:

- Perform entrance Interview.
- Tour lab.
- Observe testing.
- Interview personnel.
- Review records, data/information.
- Assess outcomes & determine compliance.
- Conduct exit conference & generate survey rept.
- Lab develops plan of correction, if problems.

CLIA Compliance for G.T. Labs

CLIA STATE SURVEYORS:

- Are professional & knowledgeable about CLIA, laboratory practices & quality assessment.
- Evaluate lab's overall ability to provide accurate results instead of individual standards.
- Receive periodic training by CMS &/or experts.
- Will receive specific, detailed training with new CLIA G.T. regs.
  - CMS will enlist nationally recognized G.T. experts.

CLIA Compliance for G.T.

- **<u>Without specific G.T. training a CLIA surveyor can:</u>**
  - Review lab director's qualifications & responsibilities.
  - Evaluate QC, instrument maintenance & analytical test validation & PT data.
  - Interview testing personnel: observe testing, reports.
  - Verify specimen integrity, I.D., handling, audit trail, confidentiality, check personnel competency, etc.
  - Assess lab's plan to assure accuracy internally & externally & solve problems;check turnaround time.
  - CMS: every lab unique; will assist w/ compliance.

CLIA Compliance for G.T.

- **CLIA experience with G.T. research labs:**
  - Much of what lab does to verify test works & results are correct facilitates meeting CLIA.
  - Existing documentation & data are useful.
  - Organizational materials are acceptable: e.g. job descriptions, safety plans, etc.

Quick CLIA 101

- **Current Status of G. T. under CLIA:**
  - Genetic Testing covered by CLIA.
  - QC & personnel stds. for Cytogenetics.
  - No genetic /molecular specialty.
  - Molecular amplification workflow, PCR QC & incr. confidentiality in ’03 CLIA regulations.

Quick CLIA 101

- **History:**
  - 1997—NIH/DOE TF rept. published.
  - 1998—CLIAC recommendations.
  - 1999—SACGT recommendations.
  - May 2000—CDC Notice of Intent (NOI).
  - 2001—revised CLIAC recommendations.
  - 2006—Notice of Proposed Rulemaking in CMS clearance.

Quick CLIA 101

- **Potential G.T. Issues for Comment**:
  - Definition
  - Informed consent
  - Clinical validity
  - Proficiency testing
  - Personnel qualifications
  - G.T. research labs reporting results

Quick CLIA 101

- **Sources of Input for NPRM:**
  - CLIAC
  - Public comments from NOI
  - Professional standards/guidelines
  - Accreditation organizations/States
  - Subject matter experts
  - Other Federal agencies

Quick CLIA 101

- **<u>Components of NPRM:</u>**
  - *Preamble*—background, history, rationale.
  - *Proposed Standards*—requirements for labs.
    - Will solicit comments.
  - *Regulatory Impact Analysis*—costs vs. benefits.
  - *Paperwork Burden*—information collection.

Quick CLIA 101

- **Next Steps:**
  - On CMS regulation schedule.
  - Assess means to address open issues.
  - Clear reg. through CMS, CDC, FDA, Sec. HHS, OMB.
  - Publish.
  - Compile and respond to comments.
  - Publish final regulation.
  - Train surveyors.
  - Develop guidance & educational materials.

Quick CLIA 101

- **Where to Find CLIA Info:**
  - CMS CLIA Web site:
    - www.cms.hhs.gov/clia/
  - CMS Baltimore CLIA Office:
    - 410-786-3531
  - Judy Yost email:
    - Judith.yost@cms.hhs.gov

CLIA Compliance -- G.T. Labs

QUESTIONS???????????