

# CLIA Update

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Judy Yost

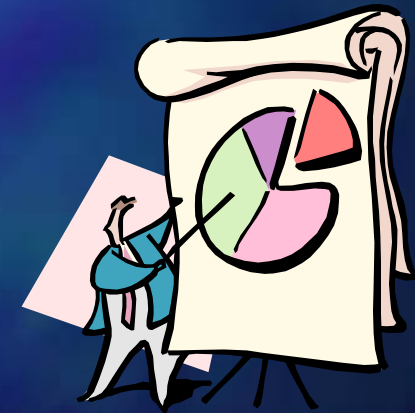
Director

Div. of Laboratory Services

CMS

# CLIA Update

- Total Enrollment—187,000 labs
- Labs by Certificate Type:
  - Compliance—21,000
  - Waiver—105,000
  - PPMP—39,000
  - Accredited—16,000
- Exempt state labs—6,000
- Source: CMS CLIA data base 8/04

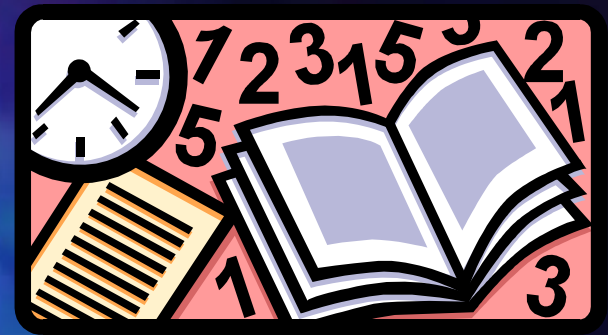


# CLIA Update



- Topics for Discussion:
  - Surveyor Guidelines on CLIA web site.
  - Surveyor training in November.
  - Educational Brochures on CLIA web site.
  - Genetic testing NPRM status.
  - QC for the Future meeting March 18, 2005.

# CLIA Update



- Final Regulation Guidelines
- Surveyor Guidelines published 1/12/04.
  - Contain regulatory citations & interpretations.
  - Surveyors use to assess compliance.
  - Labs use to meet requirements.
  - No regulatory authority; cleared by Gen. Counsel.
  - Adjustments w/ experience &/or data-early 2005.

# CLIA Update

- Surveyor training in November, '04.
  - Basic for new surveyors.
    - Includes enrollment through enforcement.
  - Advanced refresher for all surveyors on QC changes in Final regs.
    - Test method verification.
    - Calibration & calibration verification.
    - Equivalent Quality Control (EQC).
      - Re-affirmation of key P & P w/ practical applications.
  - Accrediting orgs. & exempt states invited.



# CLIA Update



- CLIA Brochures –on CMS web site.
- Developed jointly by CDC/CMS.
- #1 *Summary of Changes*
- #2 *Test Method Verification*
- #3 *Calibration & Calibration Verification*
- #4 *EQC*
- #5 *QA & General QC Tips*—under development.
- What else would you like to see?

# CLIA Update

## ■ Genetic Testing NPRM



- Joint CDC/CMS effort.
- Reflects comments from 2000 CDC NOI.
  - CLIAC & SACGT recommendations.
- Specific requirements for certain G.T.
- Some recommendations in Final CLIA regs.
  - Molecular amplification uni-directional workflow.
  - PCR QC.
  - Confidentiality.

# CLIA Update

- Genetic Testing NPRM Cont'd.
  - Open issues remain; will solicit comments:
    - Definition/scope of regulation.
    - Informed consent—CLIA authority?
    - Proficiency testing—specimens/mechanisms.
    - Clinical validity—CLIA authority?
    - Personnel qualifications.
  - No ETA!





# CLIA Update



- QC for the Future
- *Factors affecting QC:*
  - Advanced technologies/innovations.
  - Regulations/professional stds./attorneys.
  - Cost/reimbursement.
  - Personnel shortages/training.
  - Healthcare environment/error prevention.
  - Location of testing.
  - Utilization of test results.

# CLIA Update

- QC for the Future---Cont'd.
- *What are the current QC issues?*
  - Statistical validity of EQC; Six Sigma??
  - Relevance to all present & future technology.
  - Need/costs for 2 external QC each day of testing.
  - External vs. internal QC—How much? What should it monitor?
  - How to develop regs/policies that don't outdate & fit all circumstances?



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- QC for the Future---Cont'd.
- *What should we do?*
  - Work with manufacturers, lab experts, surveyors, government reps, docs.
  - To jointly discuss & plan technology & QC requirements for the present & the future.
  - To consider development of professional standards/guidance in lieu of regulations.
  - NCCLS Leadership Conference Mar. 18, 2005.
  - **COME JOIN US!!**



# CLIA Update

## ■ Where to Find CLIA Info:

### ■ *CLIA Web site:*

[www.cms.hhs.gov/clia](http://www.cms.hhs.gov/clia)

- State & regional offices, brochures, regs, data, etc.

### ■ *CMS Central office:*

410-786-3531.

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# THE END



***THANK YOU!!!***

***QUESTIONS????***