

CLIA PAST, PRESENT & THE FUTURE OF LAB MEDICINE



CLIA PAST, PRESENT & THE FUTURE OF LAB MEDICINE

Judith Yost, M.A., M.T.

Director

Division of Laboratory Services



CLIA PAST, PRESENT & THE FUTURE OF LAB MEDICINE

- **Topics for Discussion**

- *Where are we today?*

- Technology
- Personnel
- Oversight/Quality

- *Where will we be?*

- Technology
- Personnel
- Oversight/Quality



CLIA PAST, PRESENT & THE FUTURE OF LAB MEDICINE

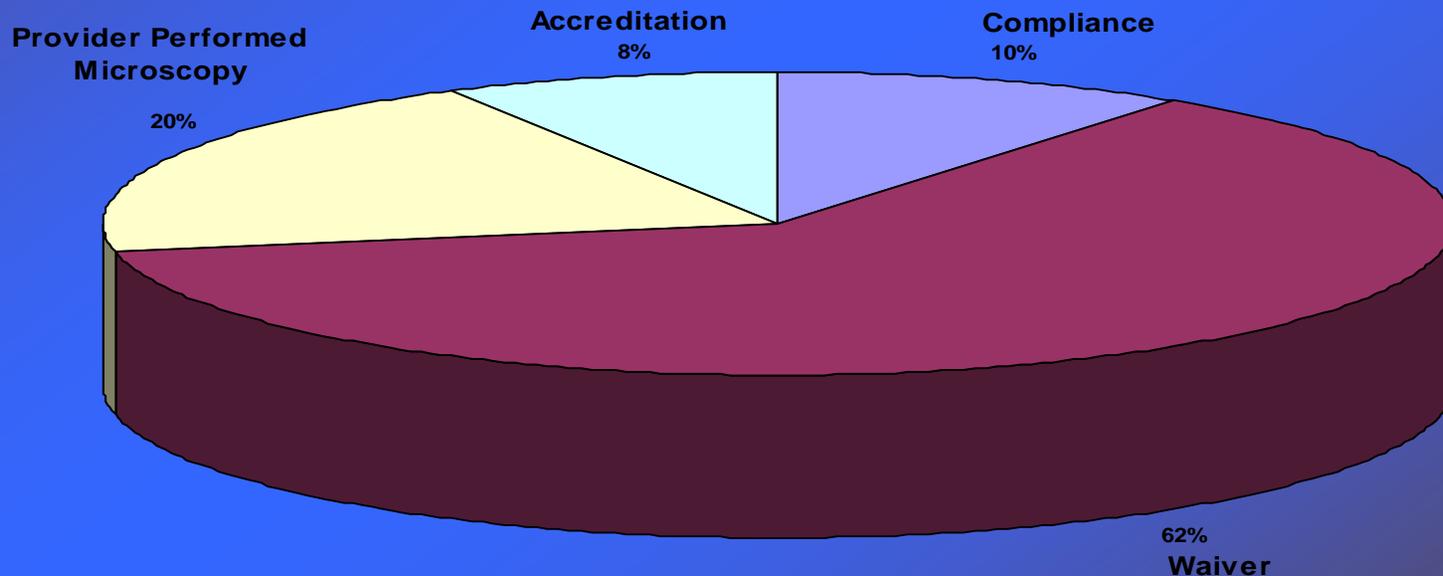
200, 667 LABS REGISTERED & growing!

- Compliance -----19,827
- Waiver ----- 119,839
- PPM ----- 38,903
- Accredited ----- 16,098
- Exempt ----- 6,000
- Note: There were 150,000 labs in 1994!



CLIA PAST, PRESENT & THE FUTURE OF LAB MEDICINE

CLIA Labs by Certificate Type (Non-Exempt Only)



CLIA PAST, PRESENT & THE FUTURE OF LAB MEDICINE

- **CLIA Labs by Certificate 1995 vs 2008:**

- **Compliance**---37,578 vs 19,695
- **Waiver**-----56,031 vs 122,992
- **PPM**-----23,089 vs 39,014
- **Accredited**-----19,426 vs 16,142

CLIA PAST, PRESENT & THE FUTURE OF LAB MEDICINE

- **Current oversight**

- Mostly regulation via:

- CMS
- AO &/or States
- Rigid standards/difficult to change



- **Future oversight**

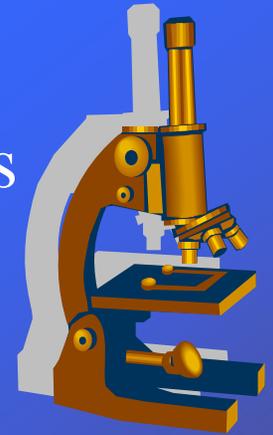
- Same, but use regs as an umbrella w/ guidance:

- Public/private partnerships
- Professional standards
- International standards
- Flexible standards/easier to adjust

CLIA PAST, PRESENT & THE FUTURE OF LAB MEDICINE

- **Current Pathology**

- Review & interpretation of microscopic slides
 - Using a standard microscope
 - In a clinical laboratory



- **Future Pathology**

- Digital pathology—images transmitted to unlimited no. of locations
 - Telepathology
 - Virtual pathology



CLIA PAST, PRESENT & THE FUTURE OF LAB MEDICINE

- **POCT**

- Continues to increase
 - 377 pharmacies in 1997; 3442 in 2008
- Technology is dynamic & robust
 - 8 waived tests in 1992; >100 in 2008
 - What will FDAs new guidance bring for the **future?**
- Explosion comes w/ issues
 - Testing personnel less-trained; may not ID problems
 - No routine oversight; no funding
 - Minimal QC



CLIA PAST, PRESENT & THE FUTURE OF LAB MEDICINE

- **Genetic Testing**

- Est. number of labs—600
- Est. number of tests---1000 and growing!
 - FDA approved----approx. 12
 - Limited PT challenges available
- 2 sides to every story:
 - Some want more regulation; others not
- Evaluating use of private/public partnerships in lieu of FDA/CMS oversight
 - CMS invited experts to collaborate



CLIA PAST, PRESENT & THE FUTURE OF LAB MEDICINE

- **Personnel shortage**

- Growth of clinical labs is >27% (BLS)
- 155,822 MTs now; will need 187,818 by 2014
- 146,626 MLTs now; will need 183,347 by 2014
- Median age is 48 yrs.
- Skill set is mobile
- Current shortfall 10,000/yr.
- National strategies underway

NOTE: Information courtesy Elissa Passiment, ASCLS



CLIA PAST, PRESENT & THE FUTURE OF LAB MEDICINE

- **Personnel shortage**

- Issues

- Recognition
 - Power
 - Work environment
 - No opportunity for advancement
 - Risk of infectious disease
 - Work hours
 - Stress
 - Wages



CLIA PAST, PRESENT & THE FUTURE OF LAB MEDICINE

- **Personnel shortage**

- Resolutions

- Send young folks to speak to young folks
- Develop HS science lesson plans
- Estab. re-training pgm. for former techs
- Encourage older techs to stay
- Include immigrants
- Brand labs as good place to work
- Employers emphasize value of techs

CLIA PAST, PRESENT & THE FUTURE OF LAB MEDICINE

- **Certificate of Waiver (CW) project**
 - CMS suspected & found problems in CW labs.
 - Conducted pilot studies:
 - Approx. 50% didn't follow mfr's instr.
 - Received support from CLIAC.
 - Initiated on site educational visits annually.
 - Intervention equals significant improvement.

CLIA PAST, PRESENT & THE FUTURE OF LAB MEDICINE

- **CW Project**
- **2004**
 - 39% not following instructions—initial visit
- **2006**
 - 34% not following instructions—initial visit
 - 70% improved conformance after intervention.

CLIA PAST, PRESENT & THE FUTURE OF LAB MEDICINE

- **CLIA retrospective thoughts**

- Balance of extremes to craft quality standards-
 - Assure access; minimize cost/burden.
 - Maintain integrity of quality oversight.
- Work w/ AOs, exempt States to improve the level & consistency of oversight-Partner's.
- Use an educational, not punitive, QA focus to survey labs & monitor outcomes (test results).

CLIA PAST, PRESENT & THE FUTURE OF LAB MEDICINE

- **Most frequent deficiencies 1995**
 - Perform 2 levels of QC-----29% of labs
 - *Establish/follow QA plan-----26%*
 - *Follow mfgr's. instructions---25%*
 - *LD responsibilities-----17%*
 - *Alt. Assessment for PT-----6%*

Italics = same deficiency as current

CLIA PAST, PRESENT & THE FUTURE OF LAB MEDICINE

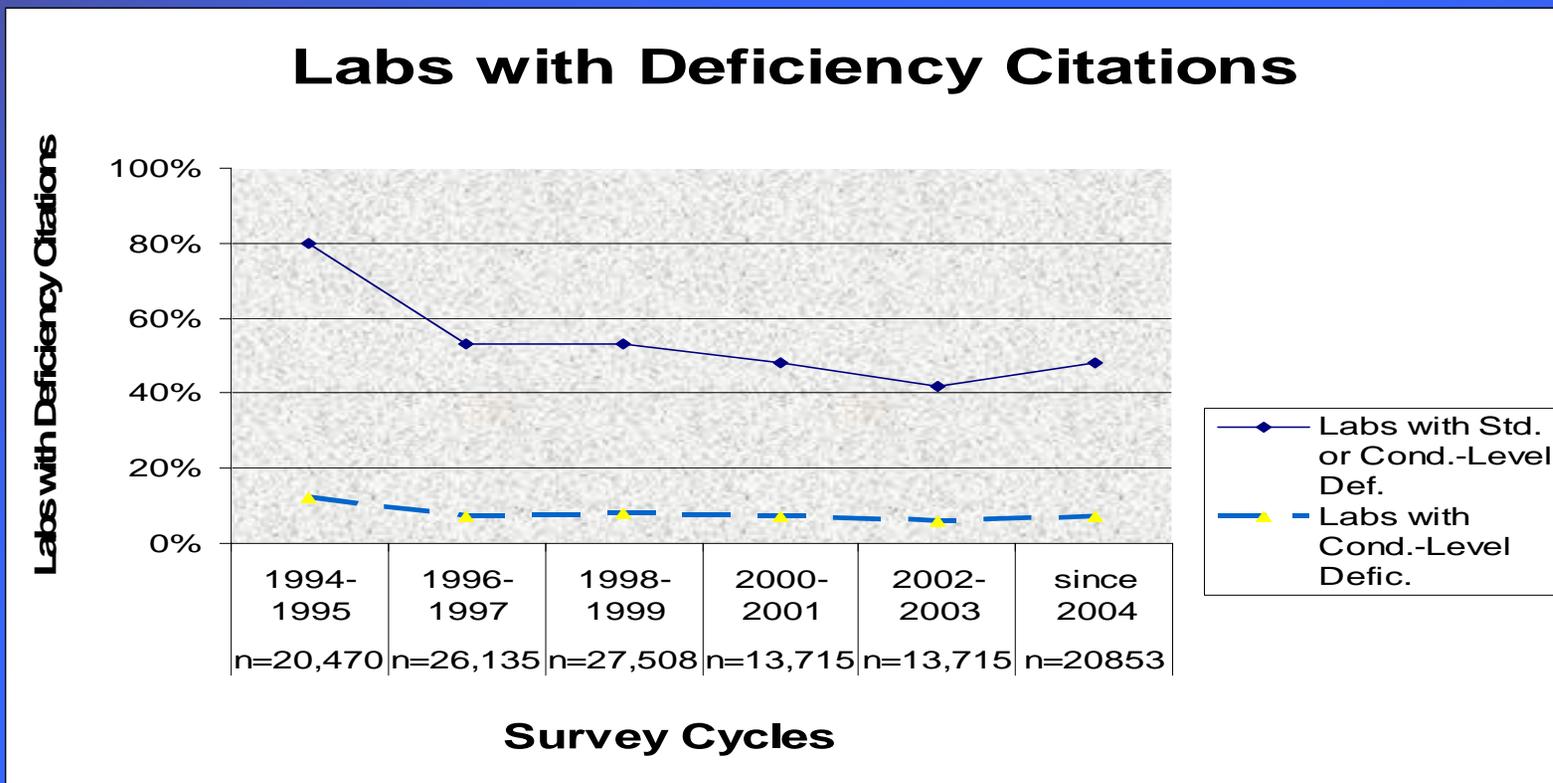
- **Most frequent deficiencies 2007**

- *Alt. Assessment for PT-----5.9% of labs*
- *Follow mfgr's. instructions---5.7%*
- *Establish/follow QA plan-----5.6%*
- *Misc. QC-----5.6%*
- *LD responsibilities-----4.2%*

Italics = same deficiency as past

CLIA PAST, PRESENT & THE FUTURE OF LAB MEDICINE

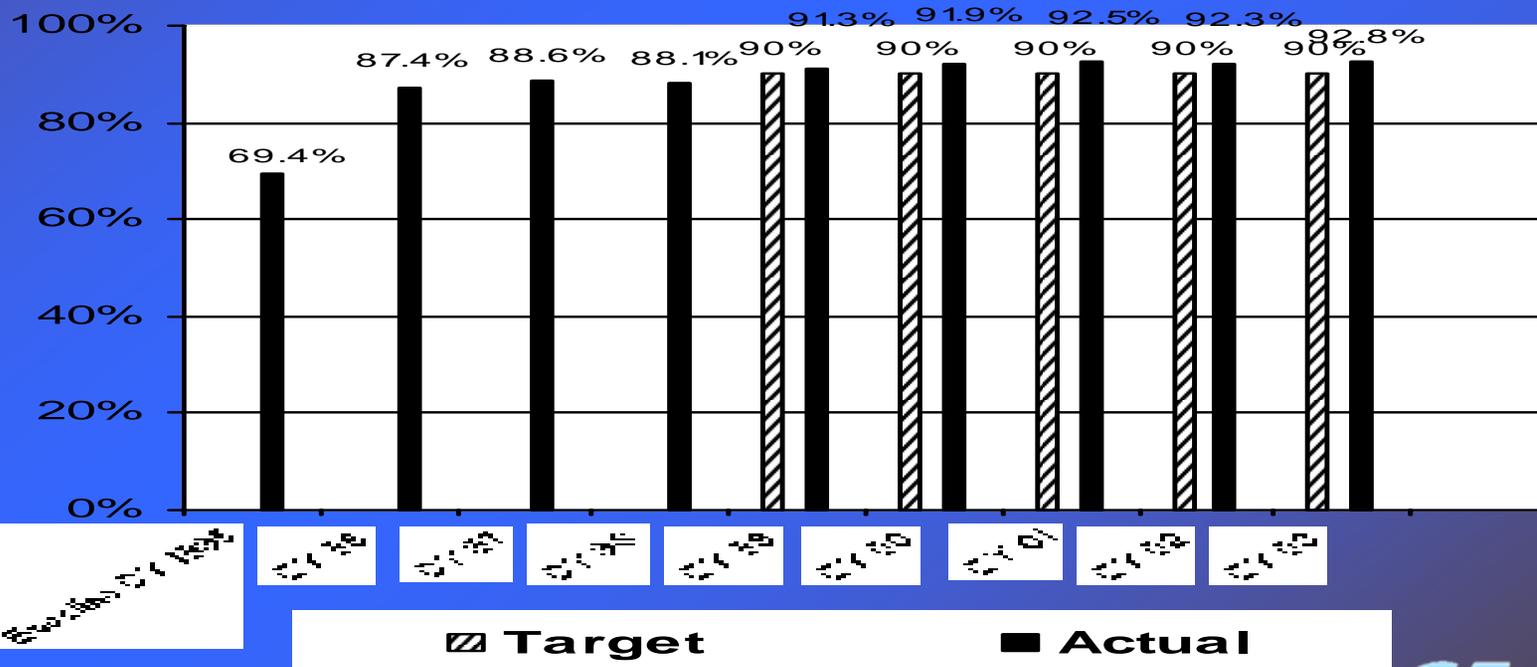
- Deficiencies



CLIA PAST, PRESENT & THE FUTURE OF LAB MEDICINE

- PT Performance

Laboratories enrolled in PT with no failures



CLIA PAST, PRESENT & THE FUTURE OF LAB MEDICINE

- **CLIA retrospective thoughts:**
 - Impetus was deaths caused by misread pap smears--
 - Last provision to be implemented was cytology PT.
 - Accurate Pap smear screening & resulting has a direct impact on the public's health!

CLIA PAST, PRESENT & THE FUTURE OF LAB MEDICINE

- **Cytology PT statistics**

- 2005 final
 - 91% passed of total tested
- 2006 final
 - 95% passed of total tested
- 2007 preliminary
 - 96% passed of total tested



CLIA PAST, PRESENT & THE FUTURE OF LAB MEDICINE

- **Goals for the Future**

- Publish standards that are more reflective of current state of laboratory medicine.
- Improve consistency among AOs, CMS regions, State surveyors, where possible.
- Use professional standards in lieu of regulations.
- Engage in public/private partnerships to garner expertise.

CLIA PAST, PRESENT & THE FUTURE OF LAB MEDICINE

- **Goals for the Future**

- Become more data driven to enhance program management & oversight.
 - Offer more lab performance data on CLIA web site.
- Ensure quality in POCT via education.
- Increase involvement in personnel shortages.
- Maintain solvency of CLIA program to guarantee laboratory quality in the U.S.

CLIA PAST, PRESENT & THE FUTURE OF LAB MEDICINE

- **Where to find more info:**
 - CMS CLIA web site
 - www.cms.hhs.gov/clia
 - CMS Central office in Baltimore
 - 410-786-3531
 - Judy Yost's email
 - Judith.yost@cms.hhs.gov



CLIA PAST, PRESENT & THE FUTURE OF LAB MEDICINE

THE END!

The future is now!

Thank you!!

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES