

CLIA—What's on the Horizon for 2007 & the Future?



CLIA Update

- Topics for Discussion:

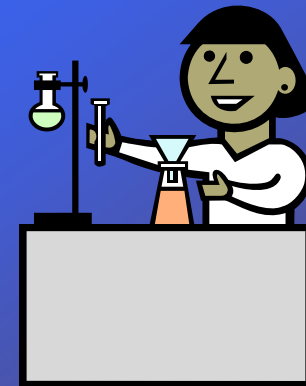
- Current Statistics
- Cytology PT NPRM
- Electronic Health Records (EHR) & CLIA
- GAO '06 CLIA Report Follow up
- Oversight of genetic testing (GT)
- CLSI EP-22 & 23: Risk Management for Manufacturers & Alternative QC for Laboratories
- Potpourri



CLIA Update

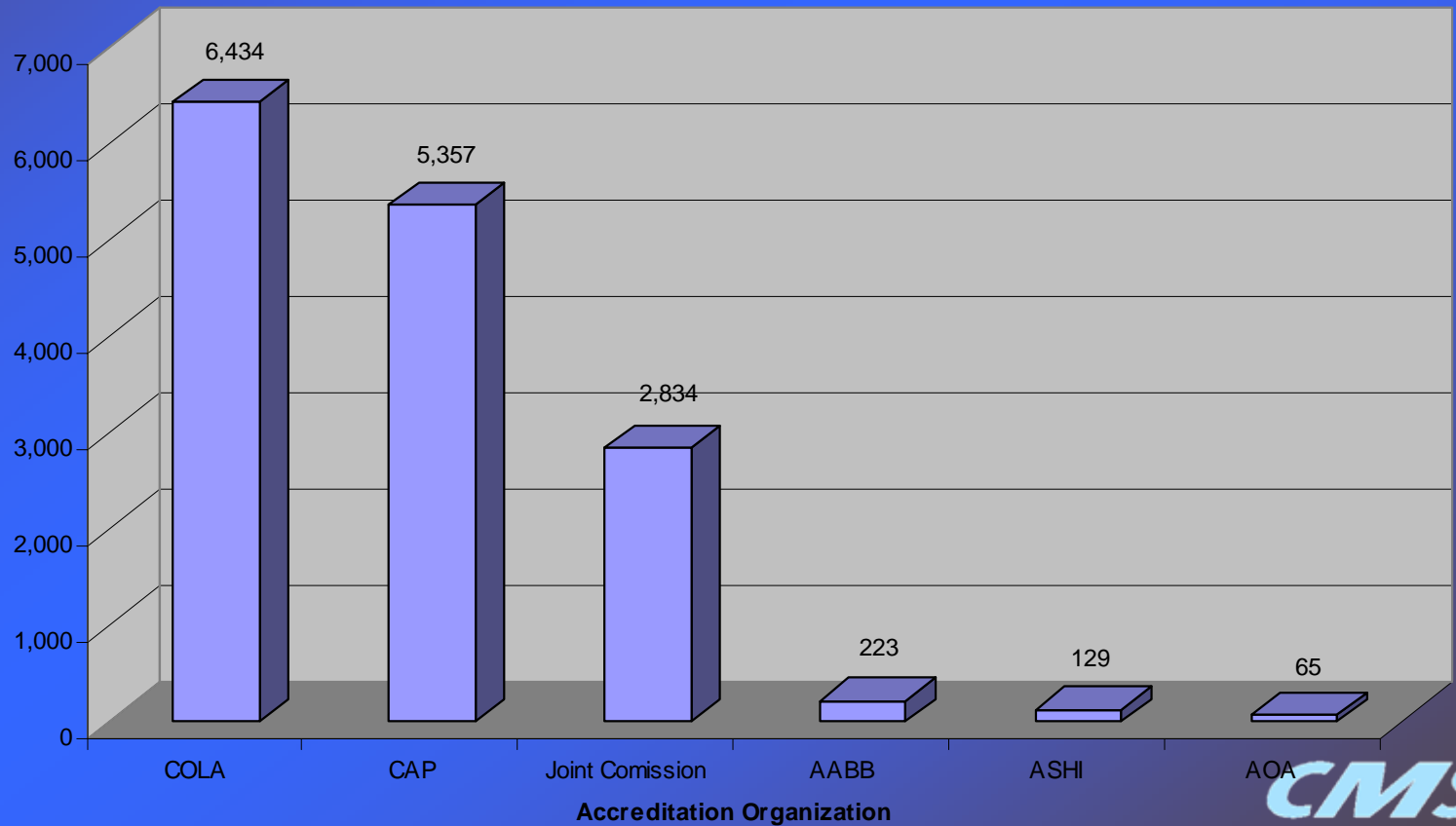
Total Number of Laboratories: 200,667!!

- Compliance: 19,827
- Waived: 119,839
- Provider Performed Microscopy: 38,903
- Accredited: 16,098
- Exempt: 6000
 - NY: 2,944
 - WA: 3,056



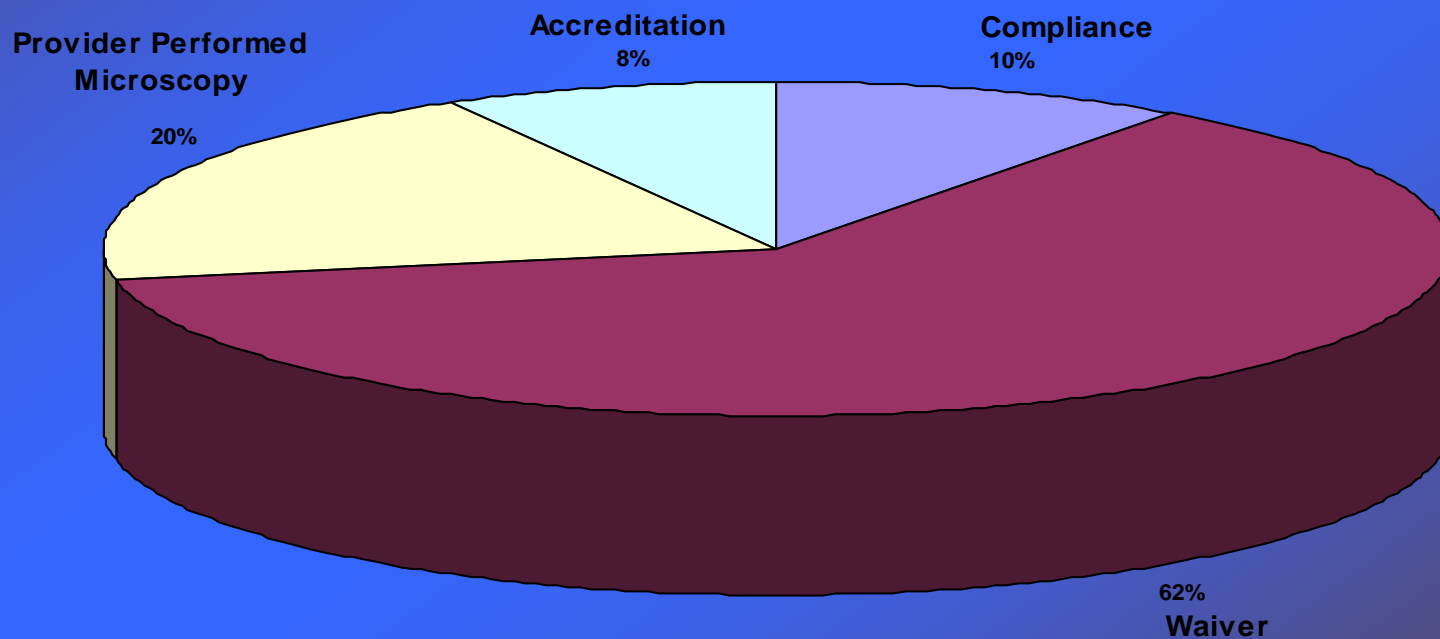
CLIA Update

Number of CLIA Certificate of Accreditation Laboratories
by Accreditation Organization



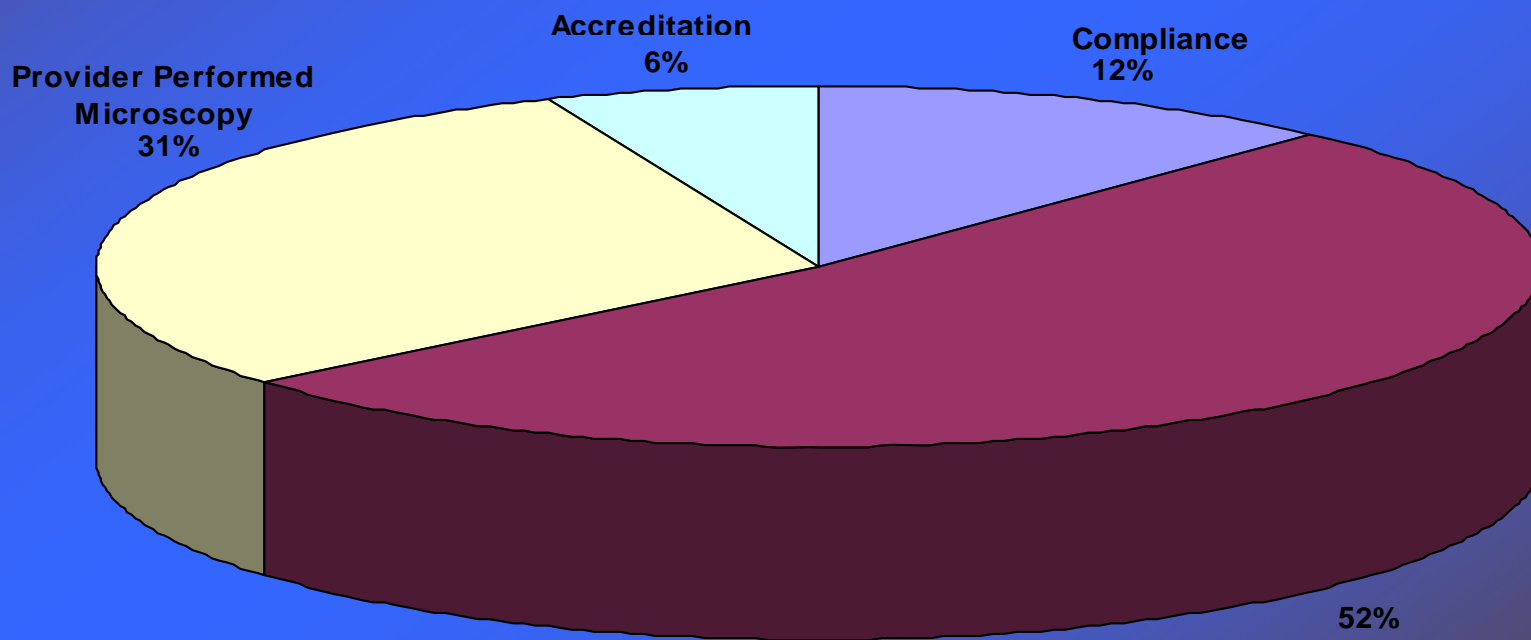
CLIA Update

CLIA Labs by Certificate Type (Non-Exempt Only)



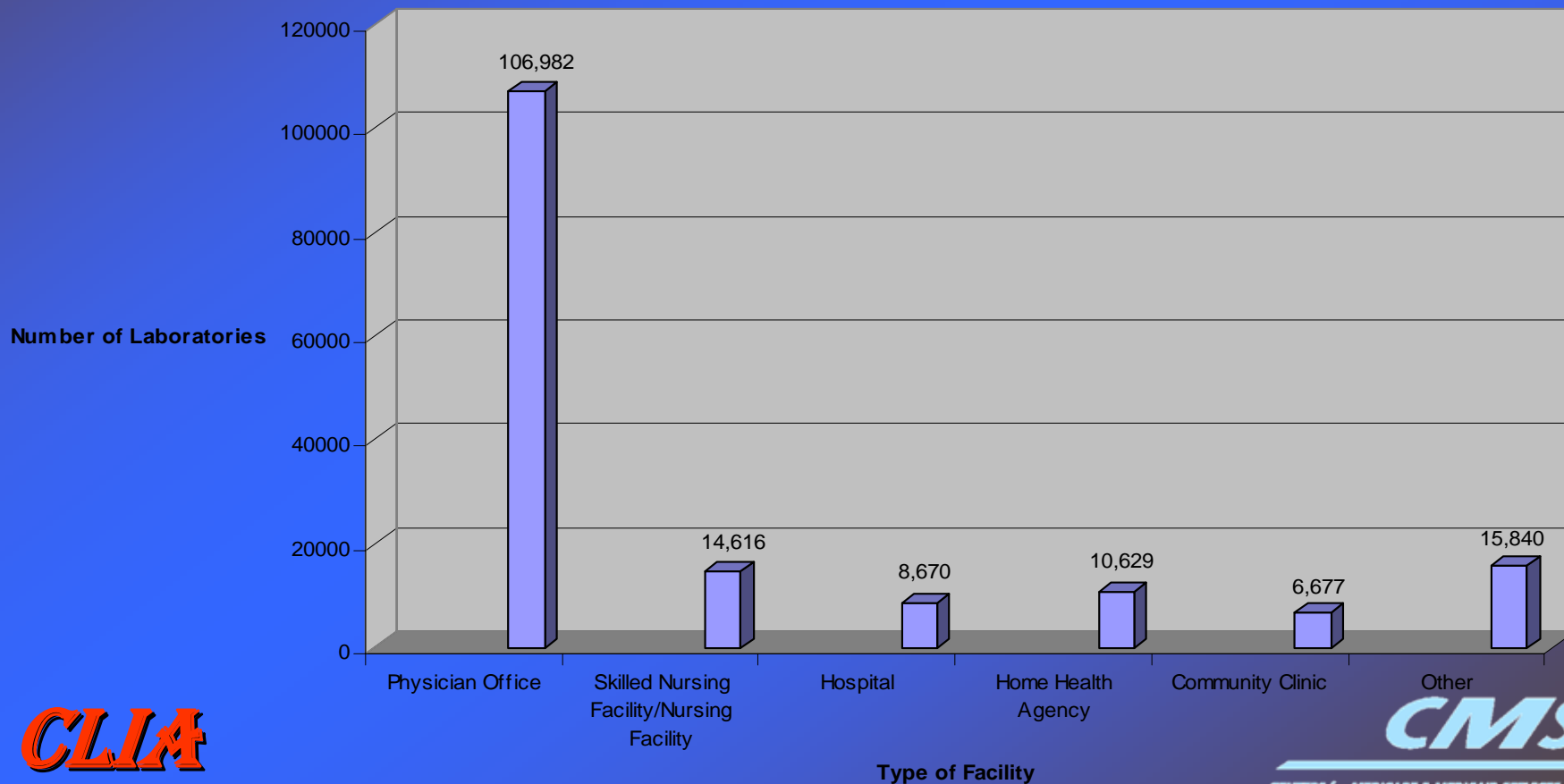
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Physician Office Laboratories by CLIA Certificate Type (Non-Exempt Only)



CLIA Update

Total CLIA Laboratories Registered Self-Selected Laboratory Types



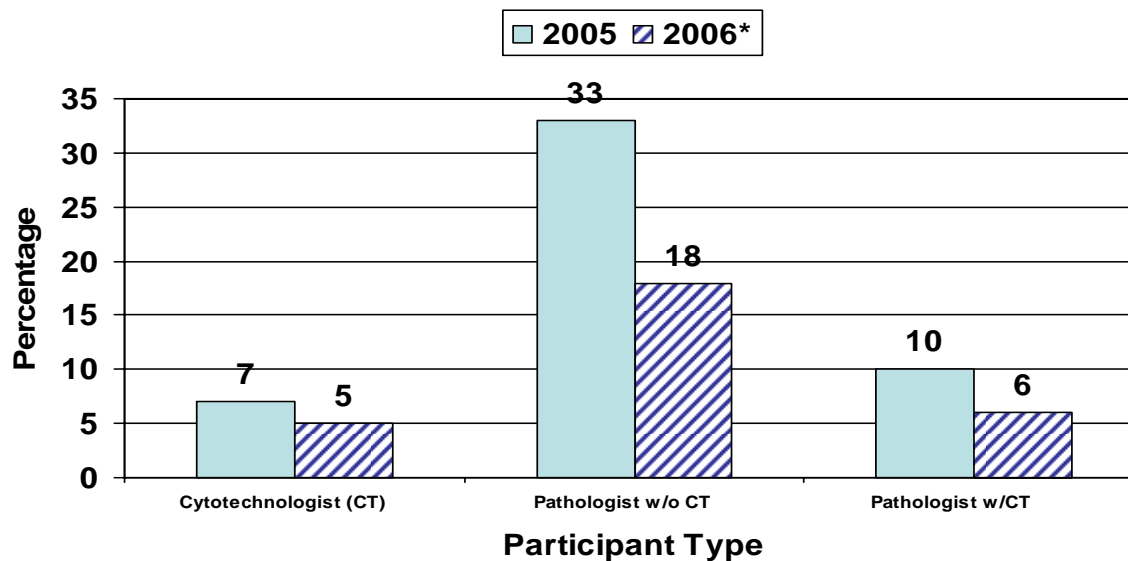
CLIA Update



- **Cytology PT NPRM (Notice of Proposed Rulemaking)**
 - Revisions demanded by cytology community, supported by CLIAC;
 - CMS offered numerous opportunities to assist with compliance, listen, educate & communicate;
 - CMS/CDC convened special CLIAC WG & mtg.;
 - CMS collaborated w/ CDC to develop NPRM.
 - Cytopath. representatives propose legislation that only requires cont. edu. to derail CLIA statutory provisions for “individual” PT.
 - *Pathologists w/o a cytotech continue to fail > others.*

CLIA Update

Failure Rates First Proficiency Test



* Preliminary 2006 data (January 1- December 5, 2006)

CLIA Update



- **Electronic Health Records (EHR)**

- Major initiative of the Secretary of DHHS;
 - Laboratories are the prototype.
- CLIA requires accurate, reliable, timely & confidential transmission of patient test results to the “user” or authorized person;
 - Also requires certain elements be included in the report.
- CMS working w/ attnys. to retain the integrity of CLIA & incur minimal burden for vendors & labs via administrative solutions, where possible.

CLIA Update

- **GAO '06 CLIA Report Follow up**
 - CMS recognized consistency problem; confirmed by '06 GAO report;
 - Conducted comprehensive surveyor training '06;
 - Scheduling add'l. focused, interactive training Oct. '07;
 - Reviewing survey & enforcement data; upgrading data system;
 - Strongly encouraging compliance for labs w/ repeat deficiencies/enforcement actions;
 - Providing detailed policies & procedures, regular conferences for regions & State surveyors;
 - Publishing updated SOM/Guidelines;

CLIA Update

GAO '06 CLIA Report Follow up --Cont'd.

- Providing more opportunities for complaints to be filed;
- Working w/ AOs to identify & monitor frequent , serious deficiencies, complaints, inconsistent policies;
- Developing performance measures for AOs, including survey timeliness;
- Requiring minimum 2 week notice for surveys;
- Improving effectiveness & timeliness of AO re-approval process;
- Recruiting & hiring technical staff;
- Monitoring State surveyor performance more closely.

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- Oversight of Genetic Testing (GT):

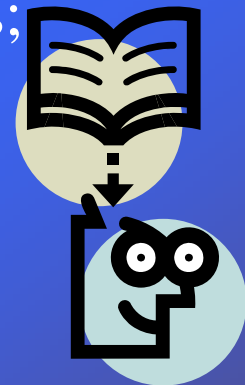
- HHS rec'd. recommendations to augment CLIA from advisory committees;
- In lieu of prescriptive regulations, increase surveyor awareness & training; develop creative survey solutions;
- New regulations won't solve paucity of PT/QC or provide clinical validity reviews;
- Conduct lab education, collect data; and
- Collaborate w/ GT community, gov't. agencies & experts to facilitate design of PT & QC options & assist w/ quality guidance.



CLIA Update

- CLSI Evaluation Protocols (EP)—22&23

- Guidance for mfr's. about risk management information for labs;
- Guidance for alternative QC protocols for labs;
- Based on the lab's unique circumstances:
 - Patient population,
 - Personnel competency,
 - Test systems utilized, and
 - Environmental issues.
- Development underway via CLSI consensus process w/ recognized experts from industry, gov't. & labs.
- When finalized, will complement or replace EQC.



CLIA Update

Potpourri of Ongoing Projects

- ❖ Partners in Laboratory Oversight
 - ❖ Collaborative efforts w/ AOs & exempt States
- ❖ Certificate of Waiver educational visits
 - ❖ Intervention demonstrates 70% of waived labs improve
- ❖ Brochure development
 - ❖ Several new ones under development; any suggestions?
- ❖ Web site enhancements
 - ❖ Lab certification info to be added
- ❖ GPRA goals
 - ❖ Routine & cytology PT data reflect improved performance over time

CLIA Update

Where to Find CLIA 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 Update

THANK YOU!!!

THE END!!

Questions???

