

CLIA Update

CLIAC March 2011

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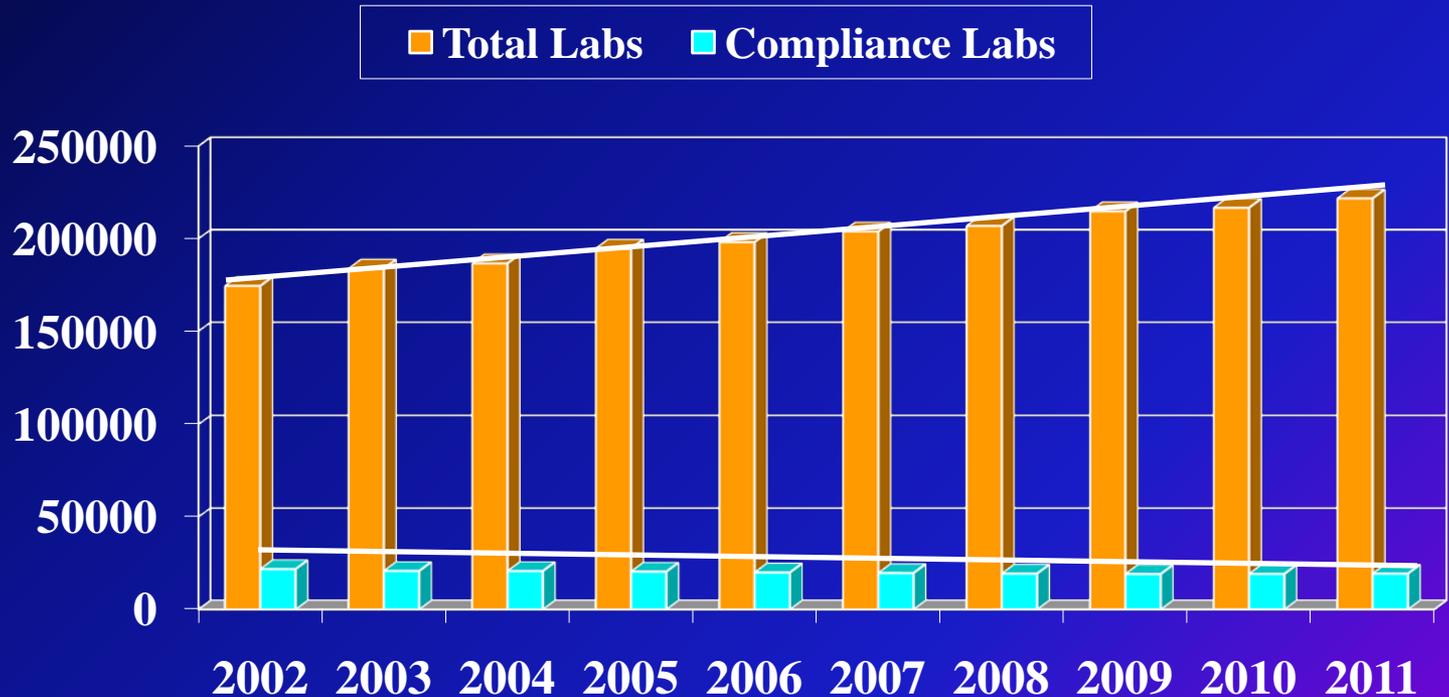


Topic Areas

- CLIA Statistics
- CMS Survey Deficiency Data
- Partners in Laboratory Oversight
- CLIA & EHRs
- Physician Signature on Lab Requisitions
- Cytology PT NPRM Update
- Waived Testing Update
- Where to Find Information

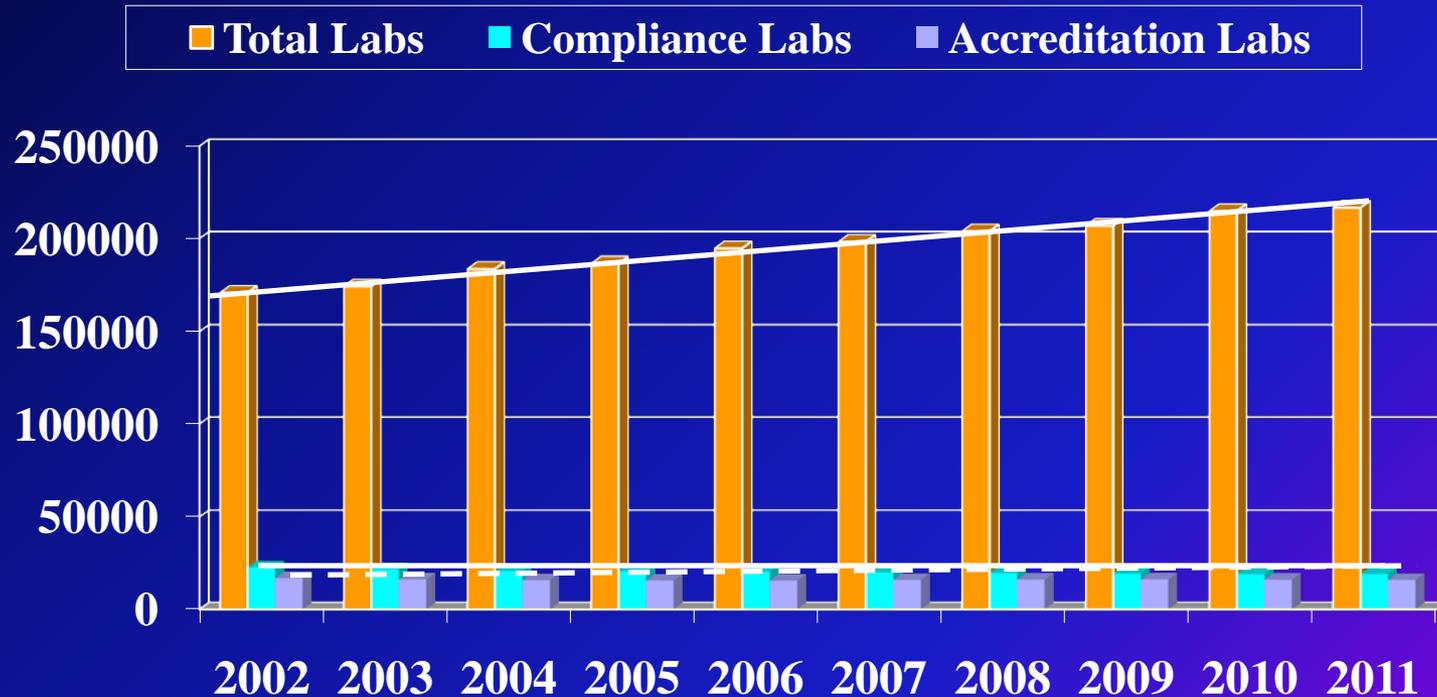
CLIA Update - General

Decade Trend



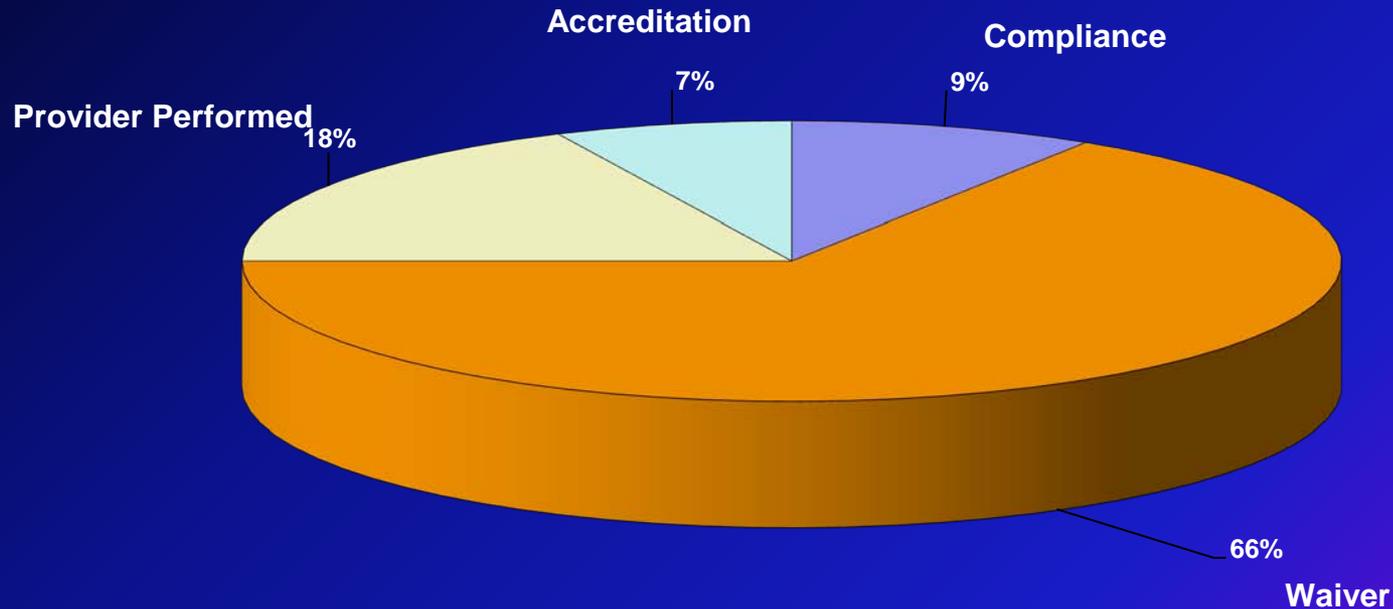
CLIA Update - General

Decade Trend



Current Statistics

CLIA Labs by Certificate Type (Non-Exempt Only)

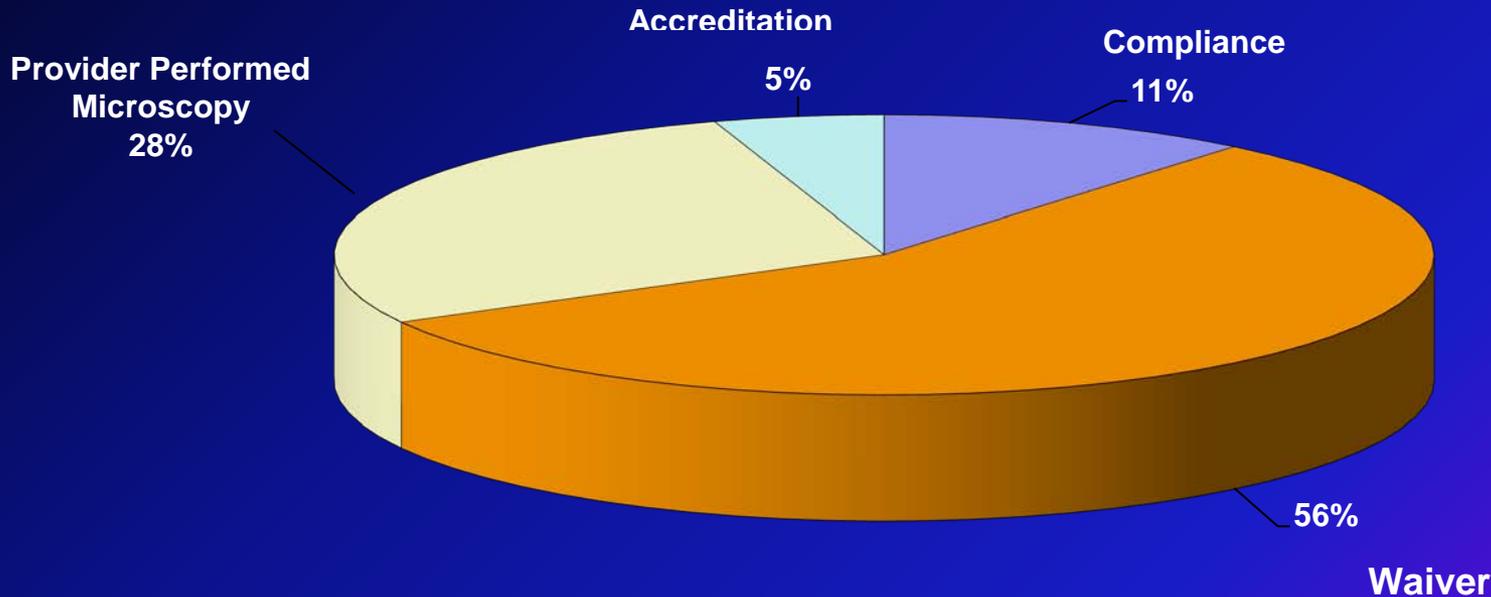


Source: CMS CLIA database 12/14/2010



Current Statistics

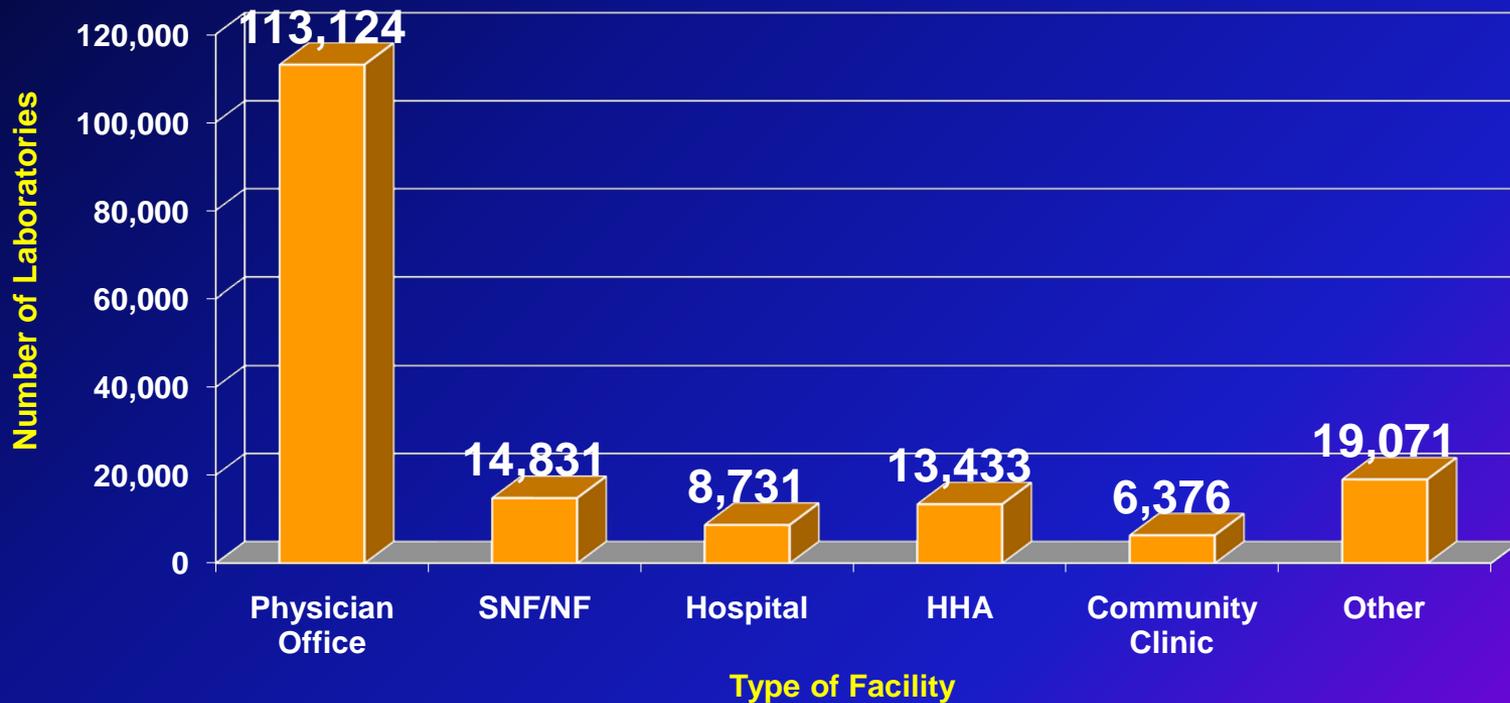
Physician Office Laboratories by CLIA Certificate Type (Non-Exempt Only)



Source: CMS CLIA database 12/14/2010

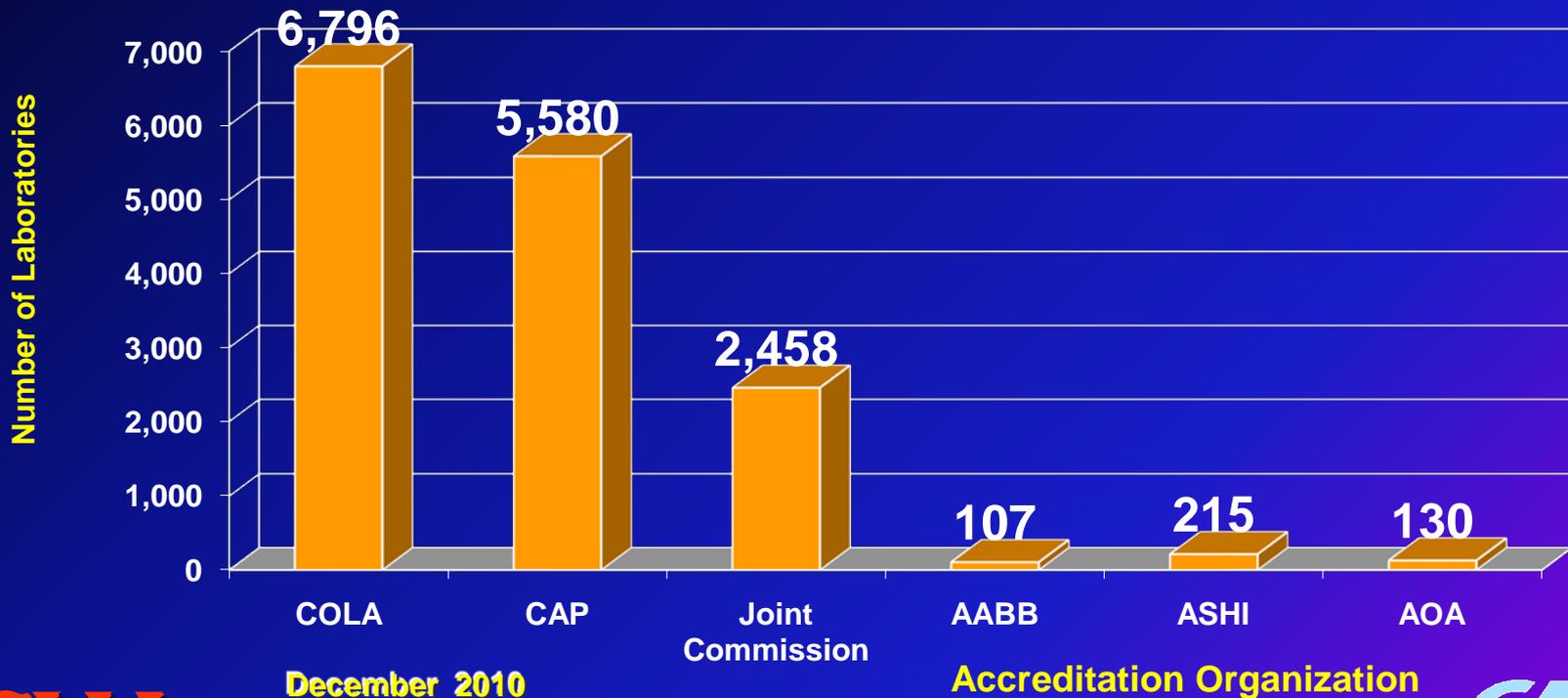
CLIA Update - General

Total CLIA Laboratories Registered
(Self-selected Laboratory Types)



CLIA Update - General

Number of CLIA Certificate of Accreditation Laboratories
by Accreditation Organization



CMS' Top 10 Condition Level Deficiencies

<u>Citation</u>	<u>% Labs Cited</u>
Mod. complexity LD qual./resp.	4.2%
Successful PT participation	3.2%
PT enrollment	1.8%
Analytic Systems (QC)	1.7%
Mod. complexity TP	1.5%

Source: CMS CLIA Database 12/10

CMS' Top 10 Condition Level Deficiencies

<u>Citation</u>	<u>% Labs Cited</u>
High complexity director qual./resp.	1.3%
Technical consultant qual./resp.	1.0%
Hematology	0.6%
Gen. Lab Systems QA	0.3%
Gen. Lab Systems preanalytic	0.3%

CMS' Top 10 Deficiencies

<u>Citation</u>	<u>% Labs Cited</u>
Policy for proper reagent storage-----	5.8%
Analytic Systems' QA-----	5.5%
Verify accuracy non-PT'd tests-----	5.5%
Follow mfgr's. instructions-----	4.9%
Procedure manual-----	4.6%

Source CMS CLIA database 12/2010

CMS' Top 10 Deficiencies

<u>Citation</u>	<u>% Labs Cited</u>
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LD responsibility-QA plan -----	4.4%
Mod. complexity LD qual./resps. -----	4.2%
Calibration verif. -----	4.2%
Use of expired reagents-----	4.1%
Gen lab systems QA-----	3.7%

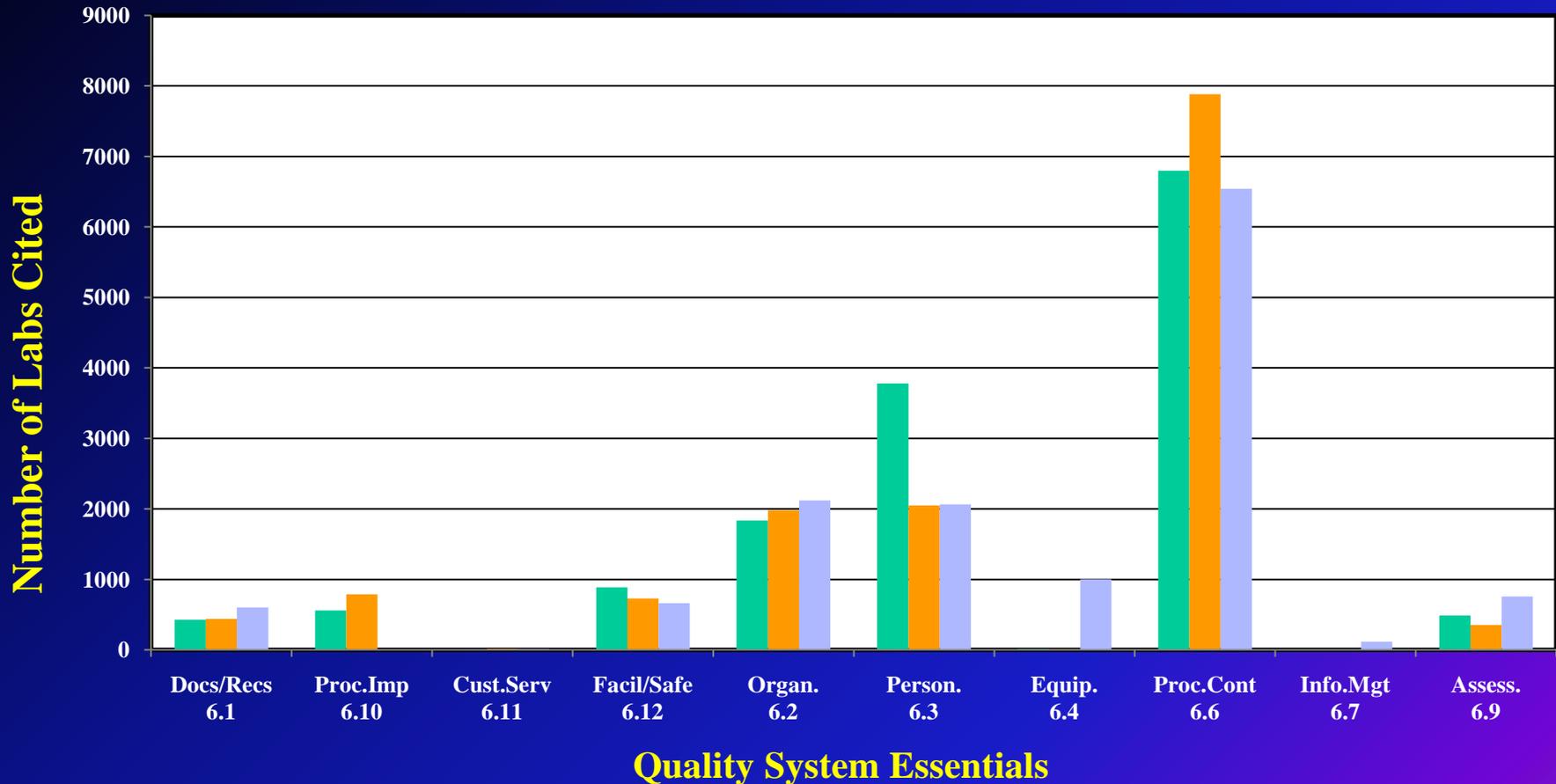
Partners

- Meeting with Partners in Laboratory Oversight since 2004
- Membership:
 - CMS CO&RO
 - AOs, Exempt States, and SAs with Licensure
 - DoD
 - VA
- <http://www.cms.gov/CLIA/downloads/090606%20RevPartners%20Lab%20Oversight.pdf>

Partners

- Common Goal:
 - Quality Laboratory Testing
- Mutual Commitments:
 - Improved communication mechanisms
 - Enhanced information-sharing opportunities
 - Greater understanding of each entity's relevant activities and policies
 - Establishment of more effective oversight programs

Partners' Deficiencies 2007-9



CMS Guidance for EHR's & CLIA

- Clarified CMS CLIA Interpretive Guidance
 - Survey and Certification Letter introduced the revisions to Appendix C (S&C-10-12-CLIA)
 - List of Frequently Asked Questions (FAQ's)
 - Expanded information, guidance & regulatory interpretations for test ordering, record retention & result reporting
 - Under the current regulations!

Future of CLIA & EHR's

- Standards & practices for electronic exchange of laboratory information are still evolving.
- CMS will revisit CLIA Interpretive Guidelines as needed to ensure that laboratories & stakeholders have clear guidance on best practices & resources to implement EHR's.
- The question of direct patient access arose.
- CMS is working on a regulatory solution.

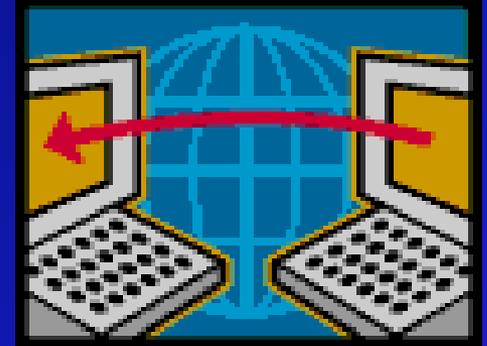
Major Health Care Reform Goal

Active involvement of patients in their own health care decisions

- Patients in control of their personal health information via access to Electronic Health Records or use of a Personal Health Record
- Access to personal health information to also include access to completed laboratory test reports
- CLIA collaborating with OCR and CDC on the best way to address patient access to laboratory test reports
- Potential changes to CLIA Interpretive Guidelines, CLIA regulations

Helpful EHR Links

- **Health Information Technology**
 - <http://healthit.gov/portal/server.pt>
- **CLIA EHR S&C package**
 - <http://www.cms.gov/SurveyCertificationGenInfo/PMSR/list.asp#TopofPage>
- **OCR Posting of Security Breaches**
 - <http://www.gov/ocr/privacy/hipaa/administrative/breachnotificationrule/postedbreaches.html>
- **FDA Safety Portal**
 - <https://www.safetyreporting.hhs.gov>



Physician Signature on Test Requisition

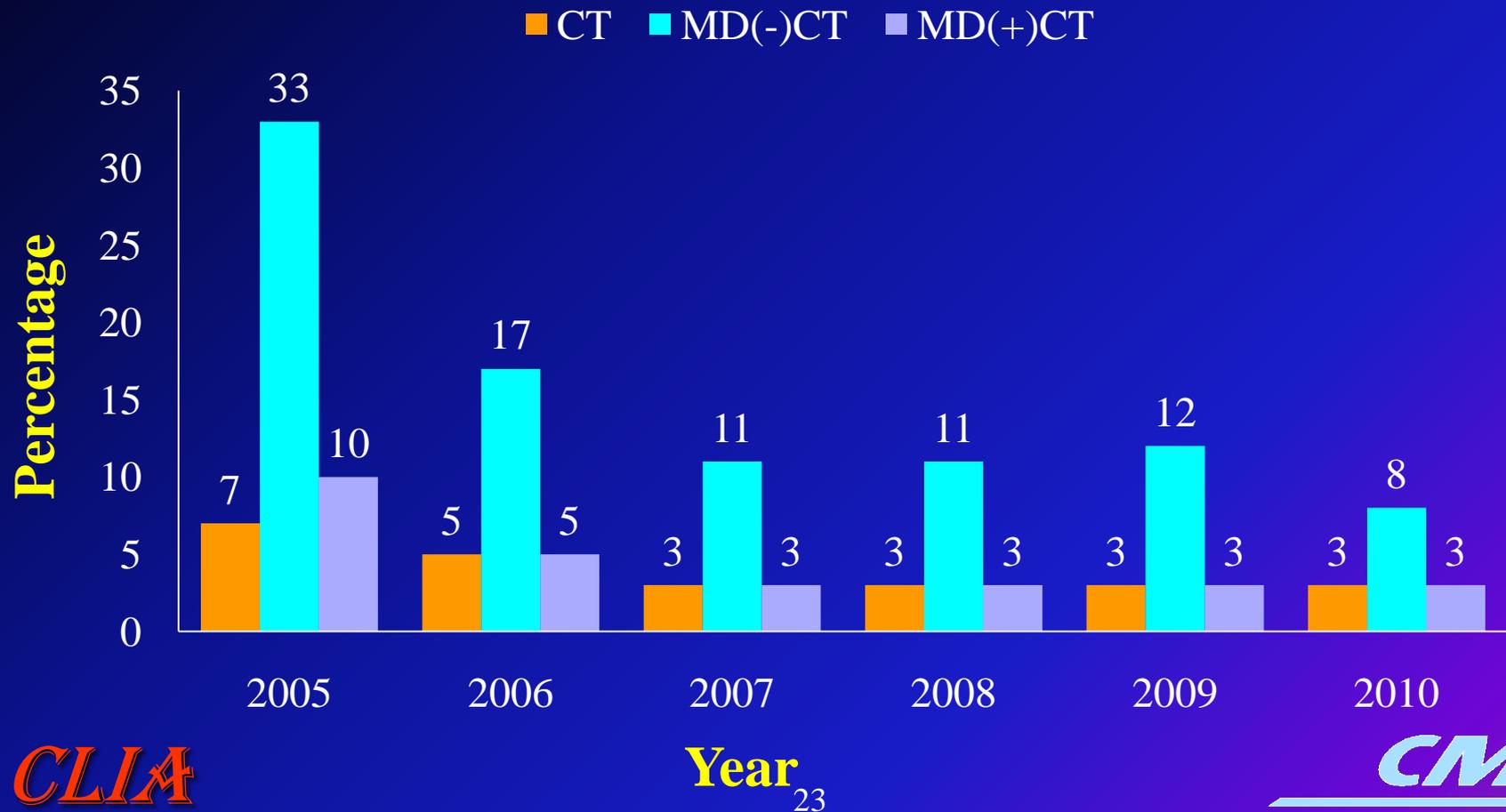
- Physician signature required on paper laboratory test requisitions under the CY2011 Physician Fee Schedule proposed rule
 - Reversal of previous Physician Fee Schedule policy
 - Does not concern electronic or telephonic requests
 - CLIA met with CMS staff on Feb.2, 2011 to discuss effects on proposal on laboratories
- **CMS now intends to withdraw the proposed rule before the April 1st effective date**

Cytology PT Update

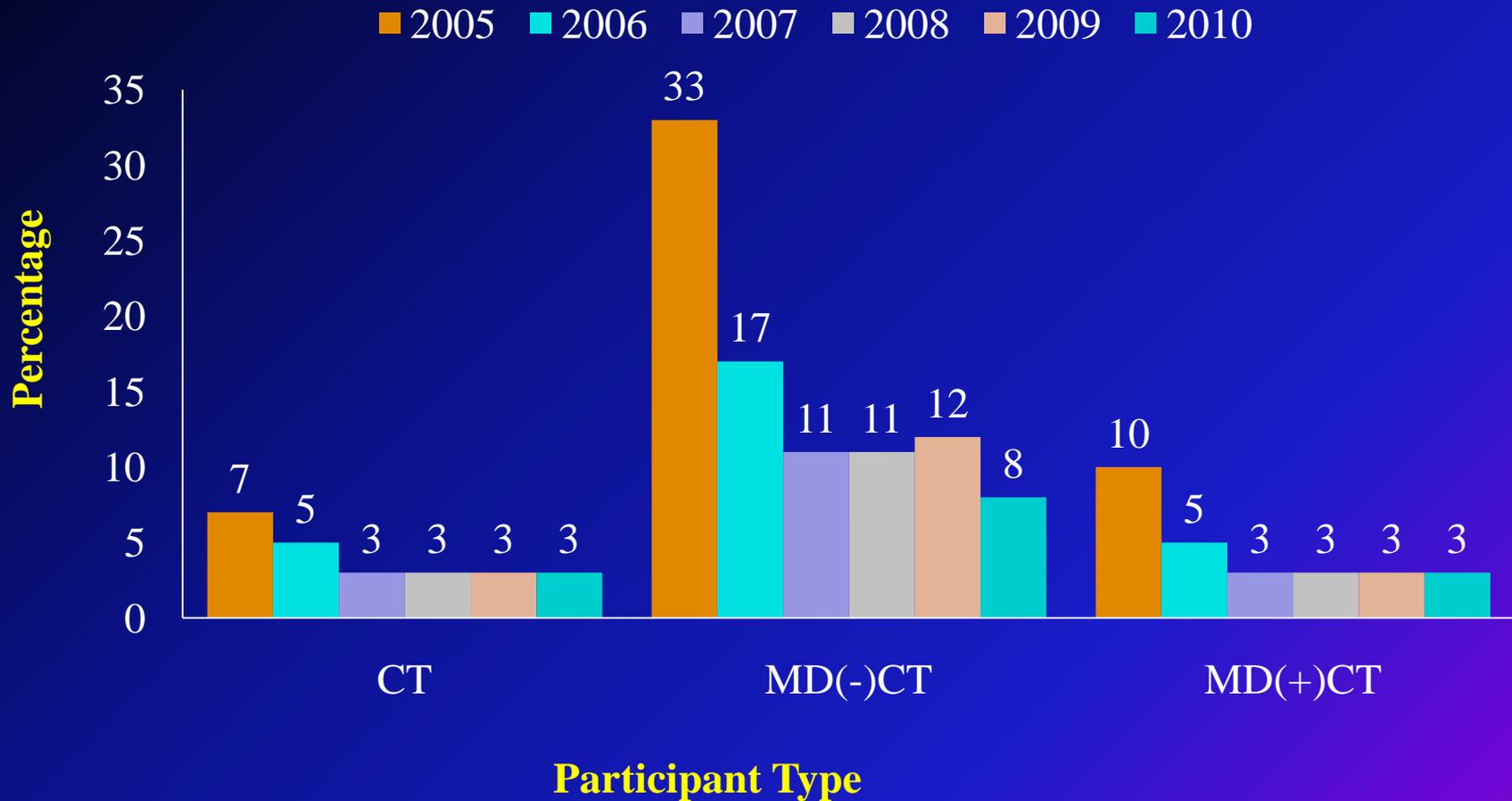
Cytology PT Proposed Regulation:

- Pub. by CMS Jan. '09; comments ended Mar. '09
- Considered 16 CLIAC recommendations
- 6000 comments rec'd. from 660 commenters
- 77% of comments did not agree w/ NPRM
- Many recommendations can be addressed w/ guidance or administratively

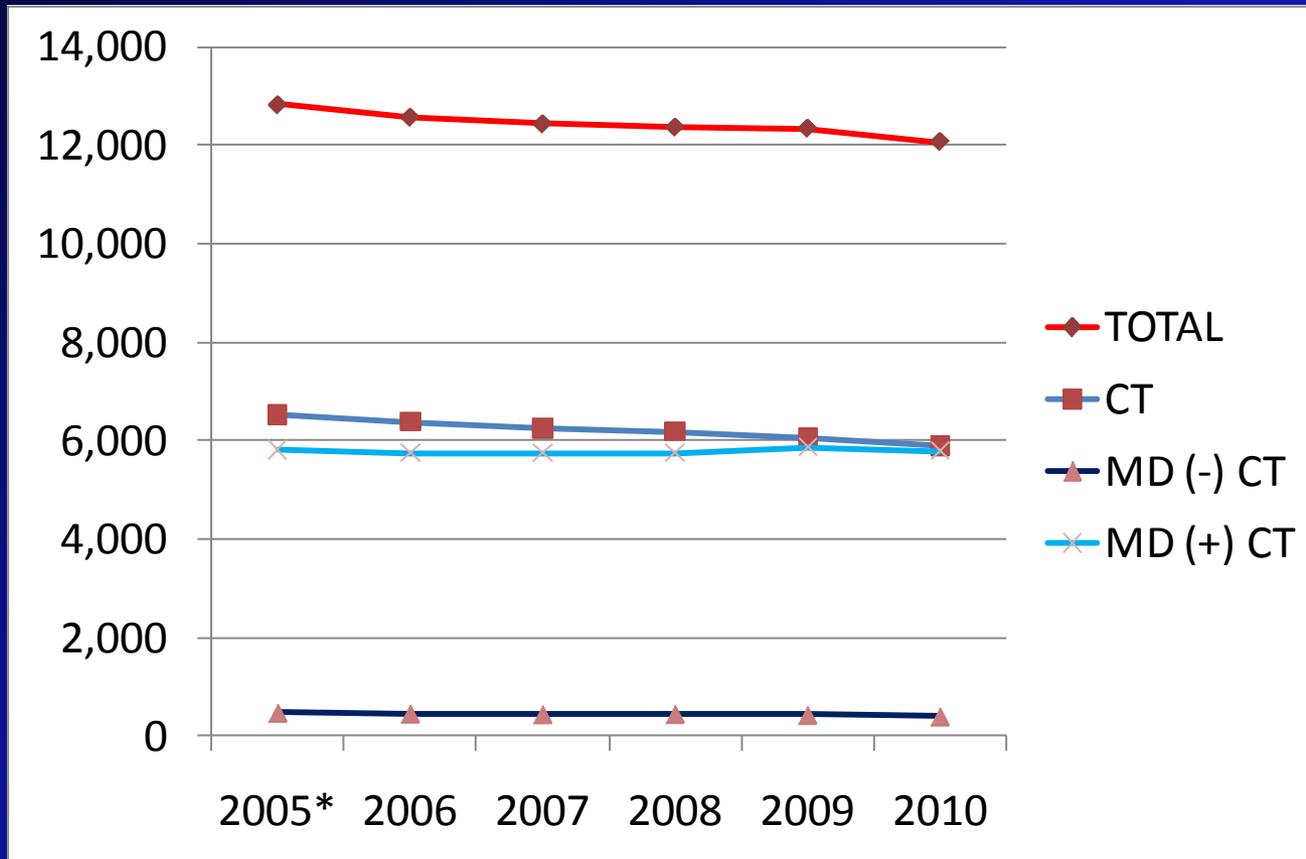
Participant Failure Rate Trends Initial Test



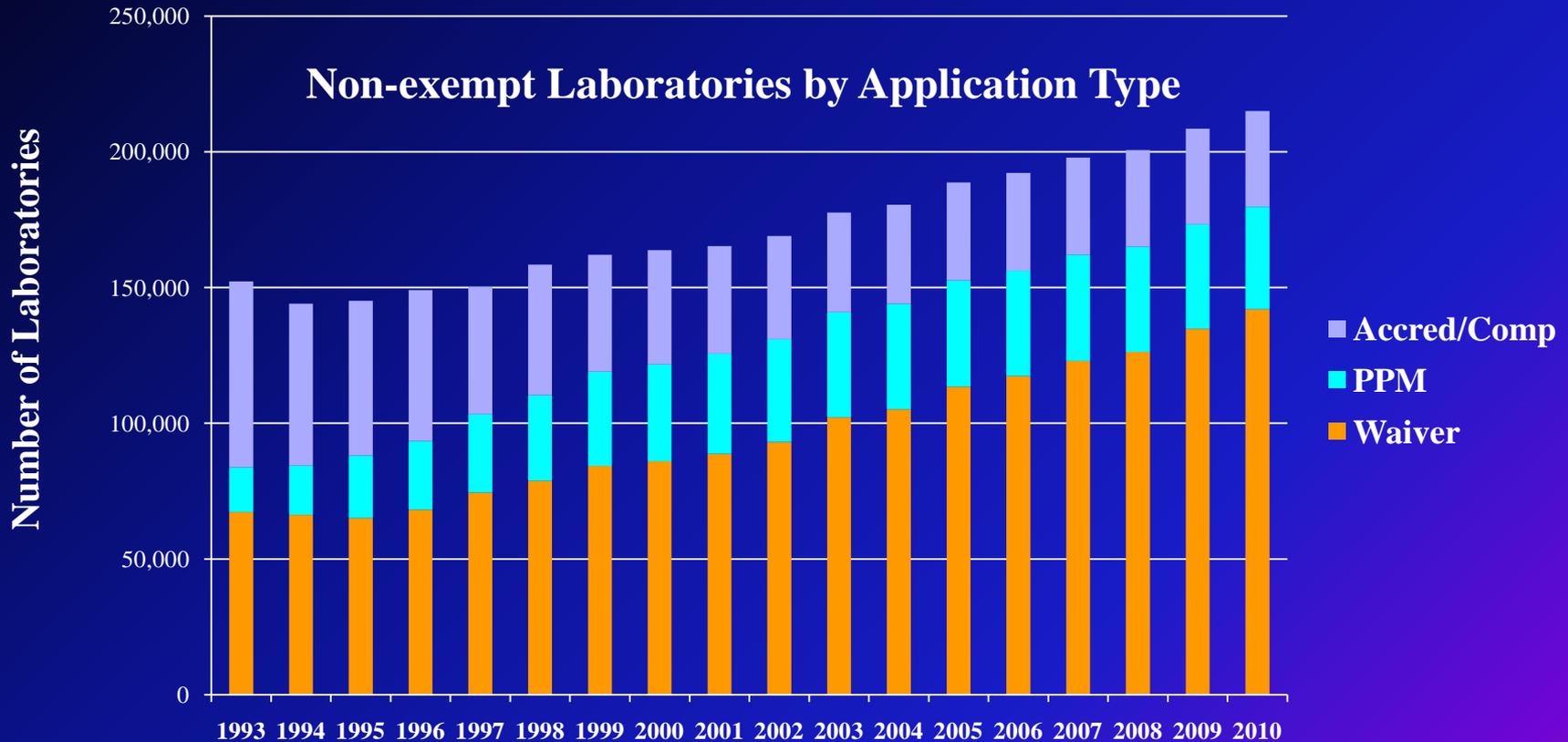
Failure Rates for Initial Test by Participant Type



Cytology PT Participation Rate (2005-2010)



CMS Waived Project -- Waived Laboratory Growth



CMS Waived Project- Complaint Scenario

- Complaint received & investigated by State & CMS regarding corporate labs w/ CW performing A1C waived testing outside its intended use at multiple locations
 - as screening vs monitoring
- Corporate web site ads misleading
- Labs also doing non-waived procedure
 - blood typing

CMS Waived Project- Complaint Scenario

- Complaint follow up is a superb example of effective coordination of CMS central (CO) & regional (RO) offices & 2 states (SA)
 - On site visit to lab; communication w/ corporate
 - Conference calls among CO, RO, SA
 - Company cooperating re compliance
 - Ongoing monitoring of test sites
 - FDA addressed intended use issue w/ manufacturer

Next Steps for Waived Testing.....

- Number of CW labs increasing exponentially
- Congress never anticipated this growth
- Education is effective, but resources are lacking
- A CMS “Issue” paper w/ multi-faceted recommendations for agency mgt. was approved
- CMS collaborating w/ stakeholders to complete long & short term plans

CMS' Plan Waived Project

Short term

- Continue CW project indefinitely
- Educate with every opportunity
- Initiate test menu collection w/ apps
- Collaborate w/ Partners/CDC /FDA
- Enlist support of professional & patient advocacy orgs
- Evaluate data from AO/ES w/ CW standards
- Publish comprehensive report

Long term

- Change the CLIA law to improve oversight

For More Information

CMS CLIA Web Site:

www.cms.hhs.gov/clia/

CMS CLIA Program:

410-786-3531

Judy Yost or Harriet Walsh via email:

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THE END

Thank you!