The Why's & Wherefore's of CLIA Competency Evaluation

Judith Yost M.A., M.T.(ASCP)
Director,
Division of Laboratory Services

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Topics for Discussion

- Introduction
- Rationale for Competency Requirements
- Competency Regulations & Procedures
- Guidance & Problems to Avoid
- Questions

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Introduction

- Personnel Competency introduced as a CLIA standard in 1992 regulations.
- Competency is required for all technical, supervisory & testing personnel.
- Various related requirements are interspersed throughout the regulations.
- Competency is NOT the same as a performance evaluation/training.

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Rationale for Personnel Competency

- CLIA's intent is to ensure accurate, reliable & timely testing.
- Studies indicate that more education & training produce higher quality results.
- The means to confirm training effectiveness is competency evaluation.
- In CLIA, the laboratory director's qualifications are stringent due to the overall quality responsibility.

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Rationale for Personnel Competency

- But qualifications for testing personnel are minimal, based on test complexity.
- Highlights importance of competency, regardless of education.
- Quality management includes personnel, processes, & procedures, as does competency.
- Competency is recognized by CLIA law.

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Rationale for Personnel Competency

- CLIA survey experience indicates many problems caused by personnel errors.
- Many laboratory test mistakes may have a patient impact.
- Routine competency evaluations will help prevent errors.
- CMS permits flexibility in achieving compliance.

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Competency Regulations

- 493.1413(b)(8)(9) & 1451(b)(8)(9)—
- Technical Consultant/Supervisor *Responsibilities—*
- *Evaluating the competency of all testing personnel & assuring that the staff maintain their competency to perform test procedures & report test results promptly, accurately, & proficiently.*

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Competency Regulations

- 493.1413(b)(8)(9) & 1451(b)(8)(9)—
- Technical Consultant/Supervisor *Responsibilities*—
- *Evaluating & documenting individuals' performance at least 2X/yr. for the 1st yr. of testing & annually thereafter, unless method or instrument changes, prior to reporting patient results; re-evaluate w/ new tests systems.*

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Competency Regulations

- 493.1235—Personnel Competency Assessment Policies—
- *As specified in the personnel requirements in Subpart M, the laboratory must establish & follow written policies & procedures to assess employee, & if applicable, consultant competency.*

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Competency Regulations

- 493.1407(e)(12) & 1445(e)(13)— Laboratory Director Responsibilities—
- *Ensure that policies & procedures are established for monitoring individuals who conduct pre-analytical, analytical & post analytical phases of testing to assure that they are competent & maintain their competency to process specimens, perform tests & report results promptly & proficiently, & whenever necessary, identify needs for remedial training or CE to improve skills.*

CLIA

CMS CENTERS for MEDICARE & MEDICAID SERVICES

Regulatory Procedures for Competency Evaluation

- Competency for all tests performed must include:
- *1. Direct observation of routine patient test performance, including patient preparation, if applicable, specimen handling, processing & testing.*

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Regulatory Procedures for Competency Evaluation

- Competency for all tests performed must include:
- *2. Monitoring the recording & reporting of test results*

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Regulatory Procedures for Competency Evaluation

- Competency for all tests performed must include:
- *3. Review of intermediate test results or worksheets, QC records, PT results, & preventive maintenance records*

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Regulatory Procedures for Competency Evaluation

- Competency for all tests performed must include:
- *4. Direct observation of performance of instrument maintenance & function checks*

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Regulatory Procedures for Competency Evaluation

- Competency for all tests performed must include:
- *5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external PT samples; and*

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Regulatory Procedures for Competency Evaluation

- Competency for all tests performed must include:
- *6. Assessment of problem solving skills*

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Competency Assessment Guidance & Problems to Avoid

- Operator training prior to testing is critical & required.
- Competency assessments must demonstrate testing personnel (TP) are performing testing accurately.
- See TP responsibilities in regulations.
- Competency assessments must be documented.

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Competency Assessment Guidance & Problems to Avoid

- Individual conducting competency assessments must be qualified.
- Competency is not PT!
- Competency records should match the laboratory's actual procedures performed by its personnel.
- When observing test performance, use the procedure manual (PM) /package insert (PI) to ensure PM is current.

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Competency Assessment Guidance & Problems to Avoid

- Can use competency assessment for QA when confirming tests ordered match reported & charted results.
- Follow up on QC corrective actions will demonstrate problem solving ability.
- Checklists are only minimally ok.
- Competency for clinical & technical consultants & supervisors is based on their regulatory responsibilities.

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Competency Assessment Guidance & Problems to Avoid

- Laboratory director serving as TC, CC, TS &/or GS isn't subject to competency requirements.
- Personnel who perform pre & post analytic activities & who are not listed in the regulations as required positions aren't subject to competency.
- But laboratory may want to do similar evaluations for QA or if a problem.

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Competency Assessment Guidance & Problems to Avoid

- Competency evaluations must be done for Provider Performed Microscopy (PPM) individuals.
- Pathologists should be evaluated by the laboratory director as technical supervisors.
- CMS permits (encourages) creativity in meeting competency requirements.

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

CMS CLIA DATA UPDATE

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

CMS CLIA DATA UPDATE

Total Number of Laboratories	**232,548**
Total Non-Exempt	**225,746**
– ***Compliance***	19,319
– ***Accredited***	15,787
– ***Waived***	146,071
– ***Provider Performed Microscopy***	37,767
– ***Exempt***	**6,802**
• *NY*	3,336
• *WA*	3,466

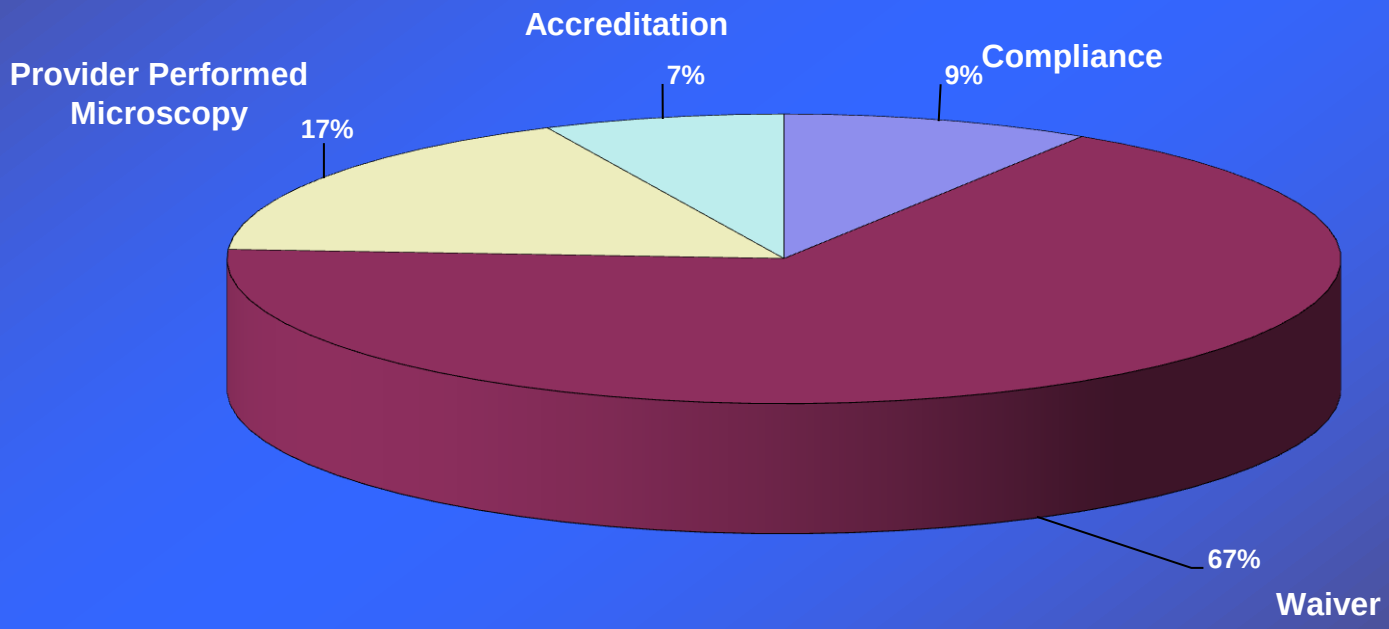
CLIA

CMS data base 6/2011

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

CMS CLIA DATA UPDATE

CLIA Labs by Certificate Type
(Non-Exempt Only)



Source: CMS CLIA database 06/2011

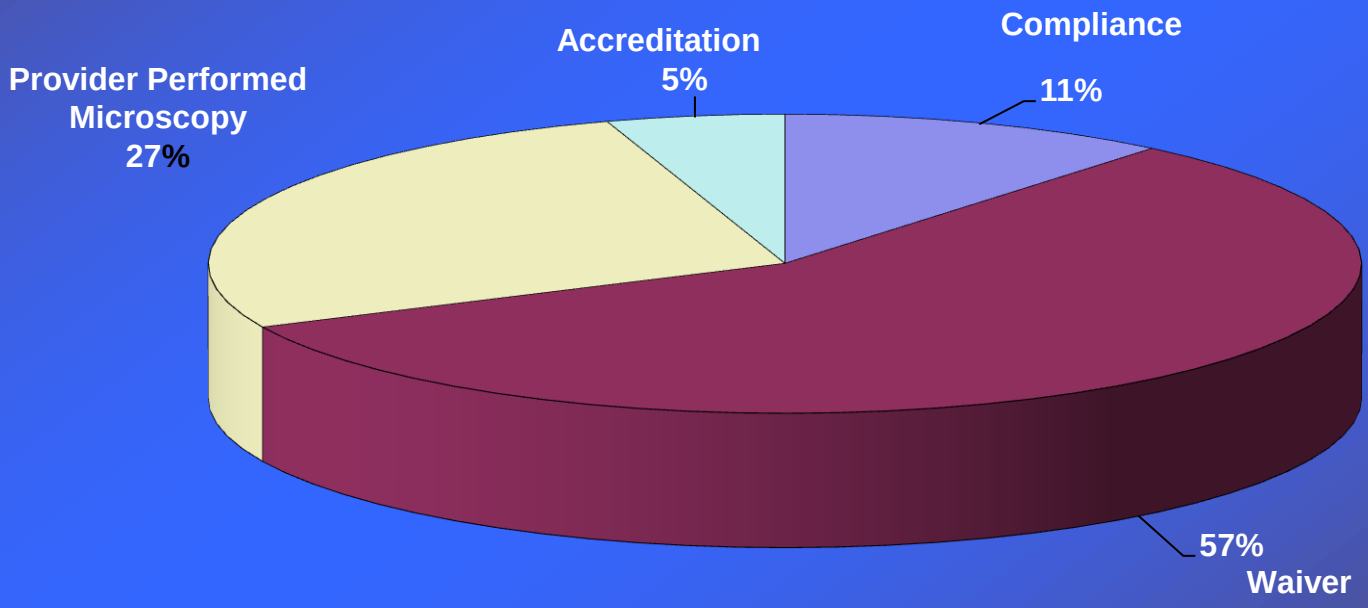
CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

CMS CLIA DATA UPDATE

Physician Office Laboratories by CLIA Certificate Type

(Non-Exempt Only)



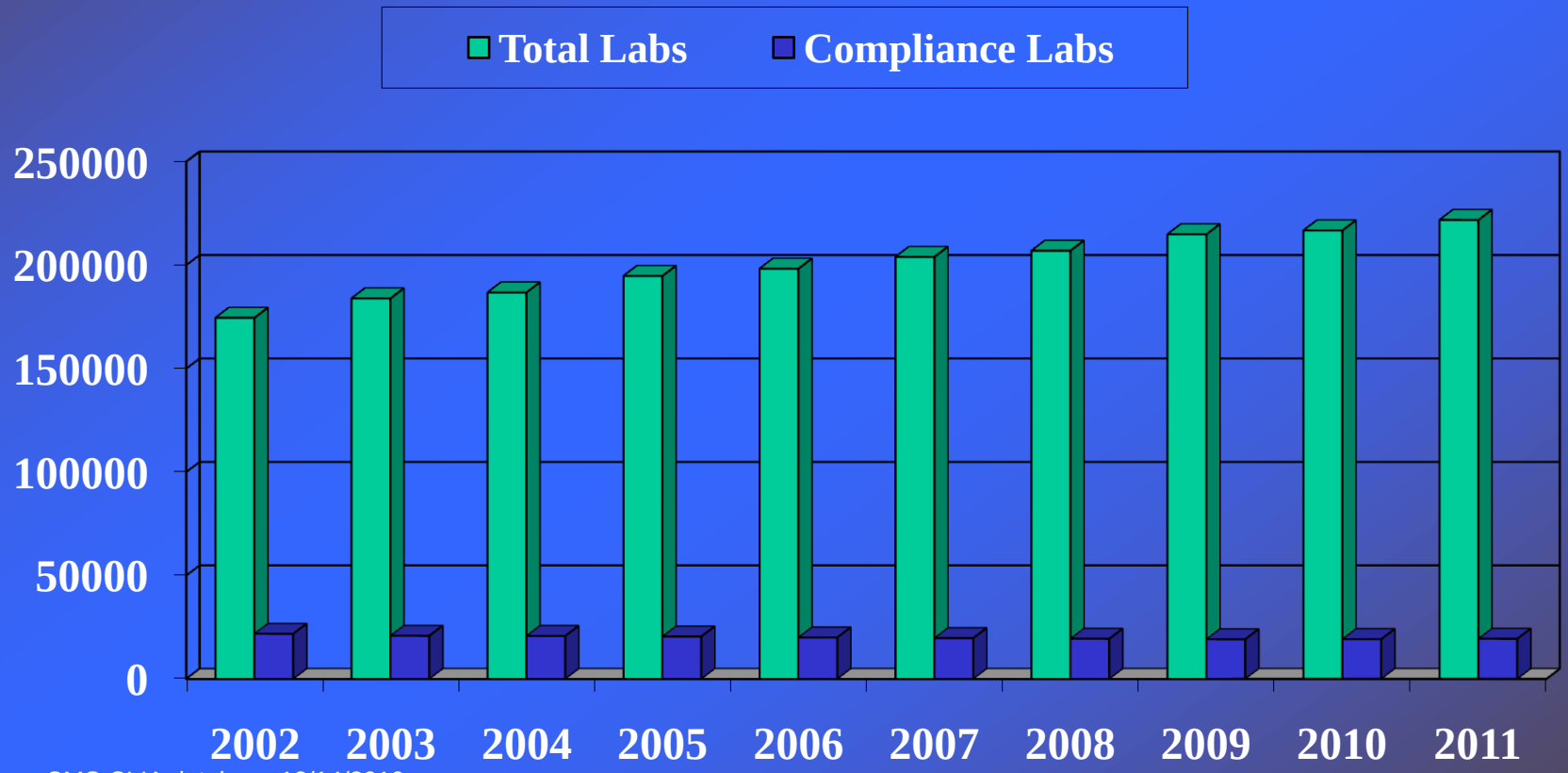
Source: CMS CLIA database 06/2011

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

CMS CLIA DATA UPDATE

Decade Trend

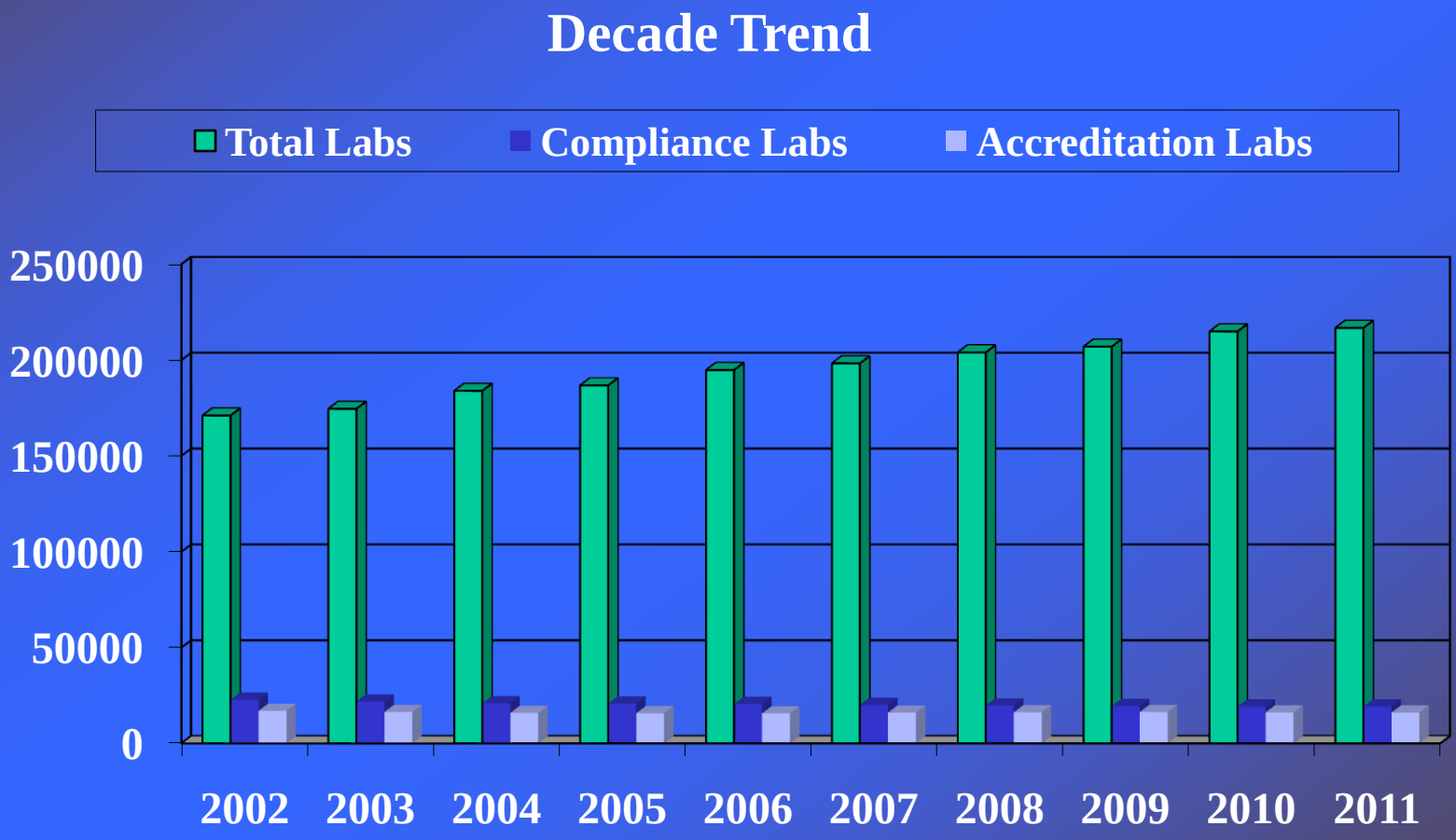


Source: CMS CLIA database 12/14/2010

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

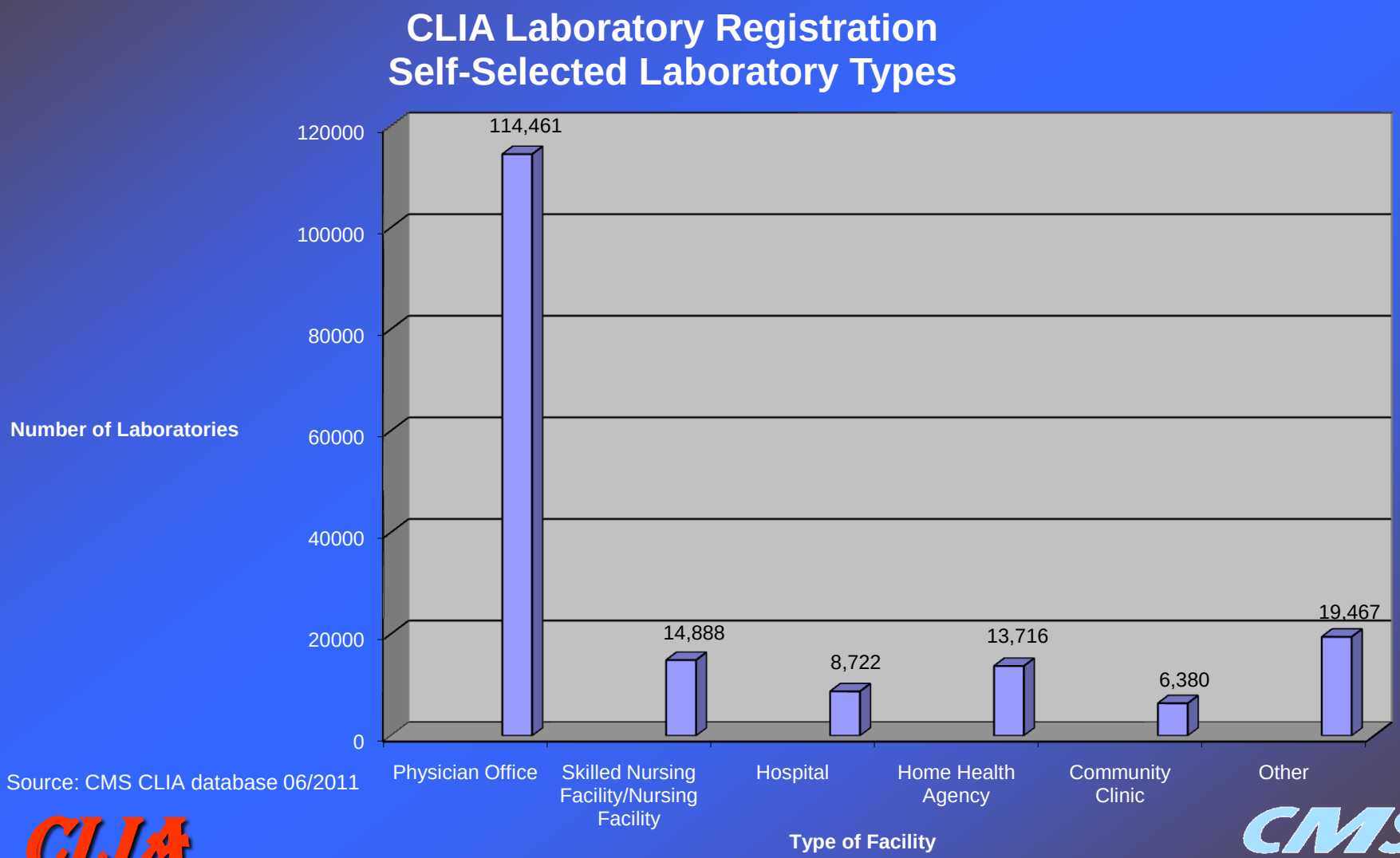
CMS CLIA DATA UPDATE



CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

CMS CLIA DATA UPDATE



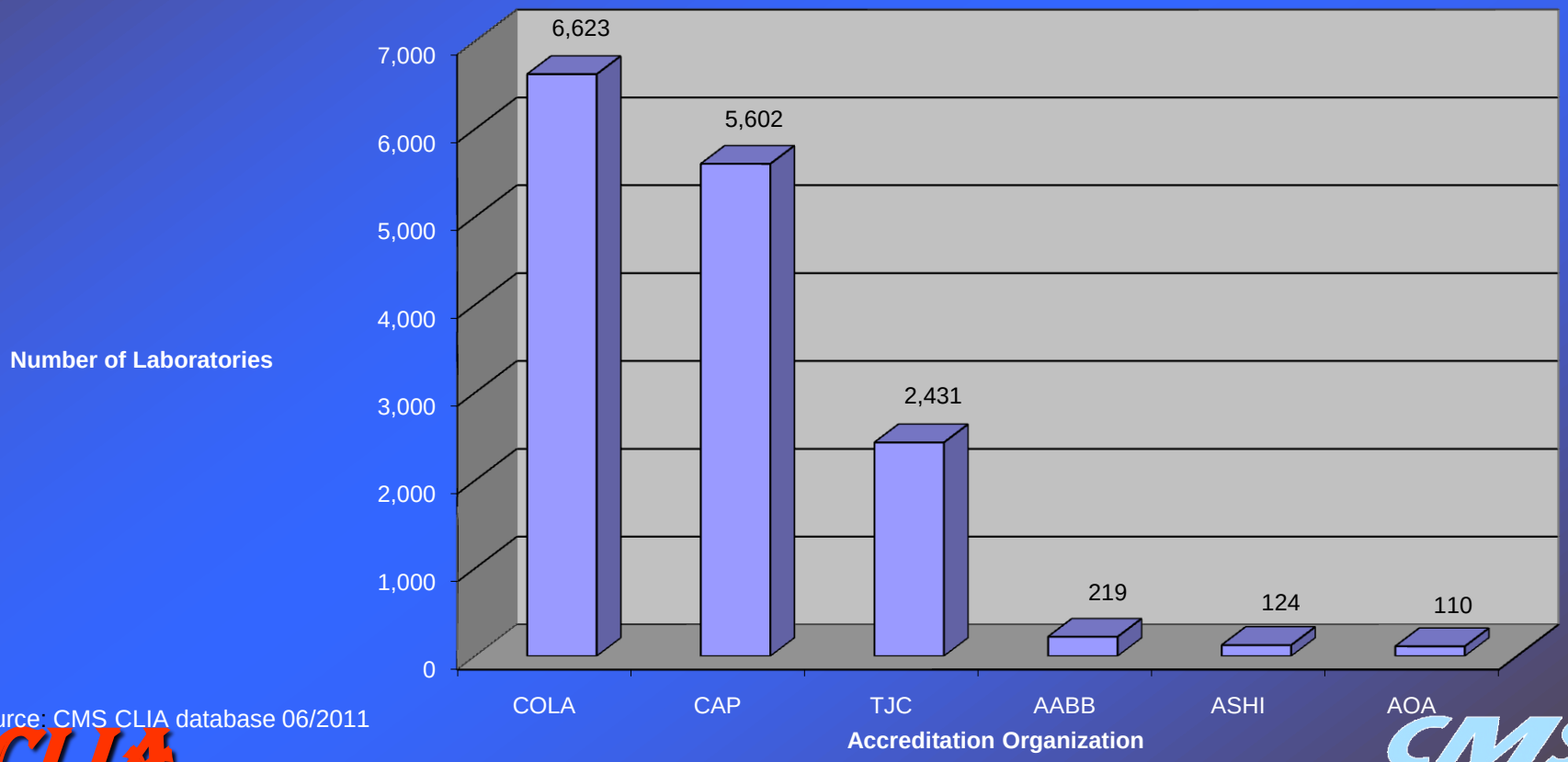
Source: CMS CLIA database 06/2011

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

CMS CLIA DATA UPDATE

Number of CLIA Certificate of Accreditation Laboratories by Accreditation Organization



Source: CMS CLIA database 06/2011

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

CMS CLIA DATA UPDATE
Transfusion Fatalities

Type	FY 2010	FY 2009
TRALI (Transfusion Related Acute Lung Injury)	36	31
Hemolytic (Immune)	9	12
TACO (Transfusion Related Circulatory Overload	5	9
Bacterial Contamination	5	6
Other (Anaphylactic, Graft vs. Host Disease, Babesiosis, Hyperhemolysis Syndrome, Allergic, Non-Immune Hemolytic, Unknown)	16	17
TOTAL	71	75

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

CMS CLIA DATA UPDATE
Transfusion Fatalities

	FY 2010	FY 2009
Investigations	4	11
2567's	0	7

2567's issued

Specimens mixed up in the lab

Specimen drawn from the wrong patient

Testing errors—missed antibodies

Wrong FFP type issued

Wrong patient transfused

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

CMS CLIA DATA UPDATE
Top 10 Condition Deficiencies

Citation	% Labs Cited
-Mod. complexity LD qualif./respons.	4.2%
-Successful PT participation	3.2%
-PT enrollment	1.8%
-Analytic Systems (QC)	1.7%
-Mod. complexity TP	1.5%

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

CMS CLIA DATA UPDATE
Top 10 Condition Deficiencies

Citation	% Labs Cited
-High complexity director qualif./respons.	1.3%
-Technical consultant qualif./respons-.	1.0%
-Hematology	0.6%
-Gen. Lab Systems QA	0.3%
-Gen. Lab Systems preanalytic	0.3%

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

CMS CLIA DATA UPDATE
Top 10 Deficiencies

Citation **% Labs Cited**

- 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%

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

CMS CLIA DATA UPDATE

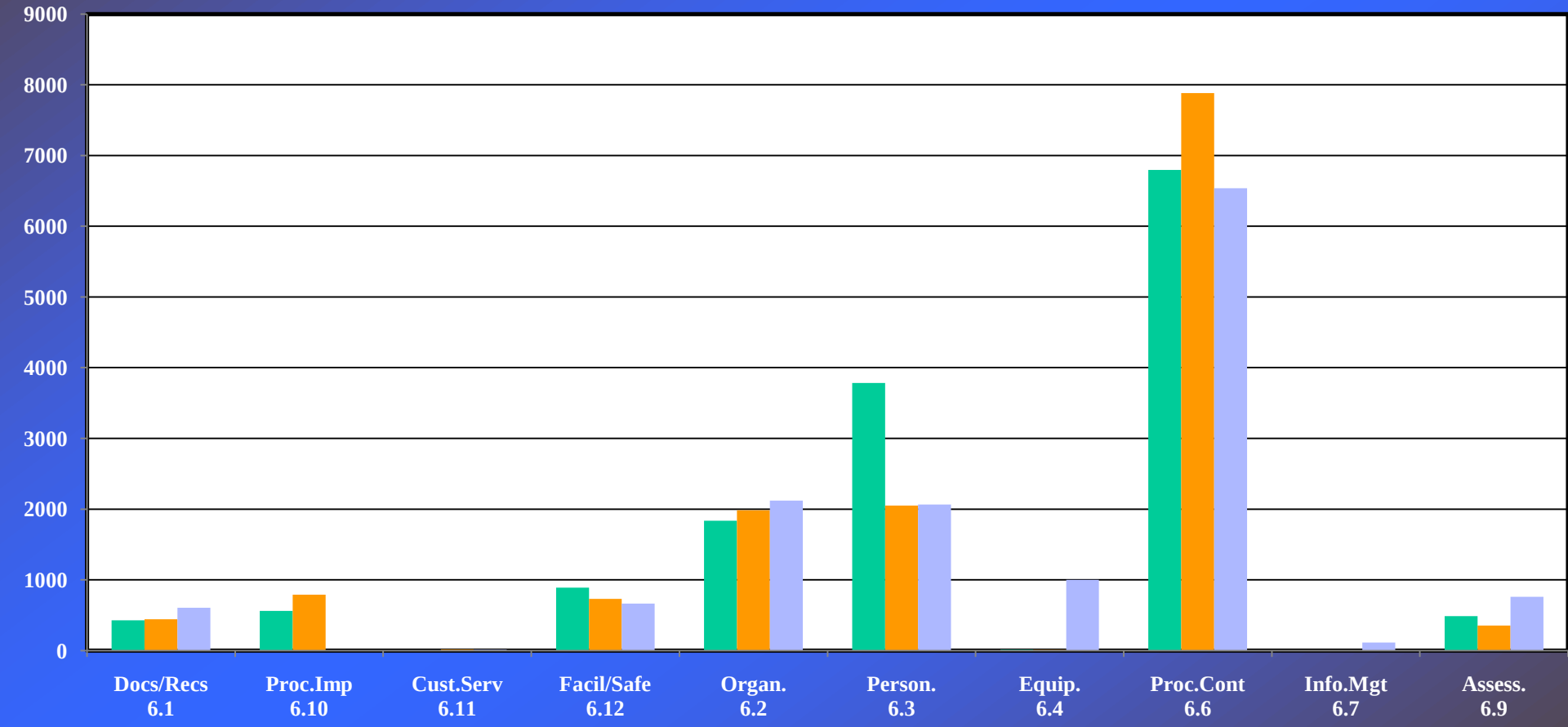
Citation **% Labs Cited**

- LD responsibility-QA plan----------4.4%
- Mod. complexity LD qualif./respons.---------4.2%
- Calibration verif.----------4.2%
- Use of expired reagents----------4.1%
- Gen lab systems QA----------3.7%

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

CMS CLIA DATA UPDATE
Partners' Deficiencies 2007-9

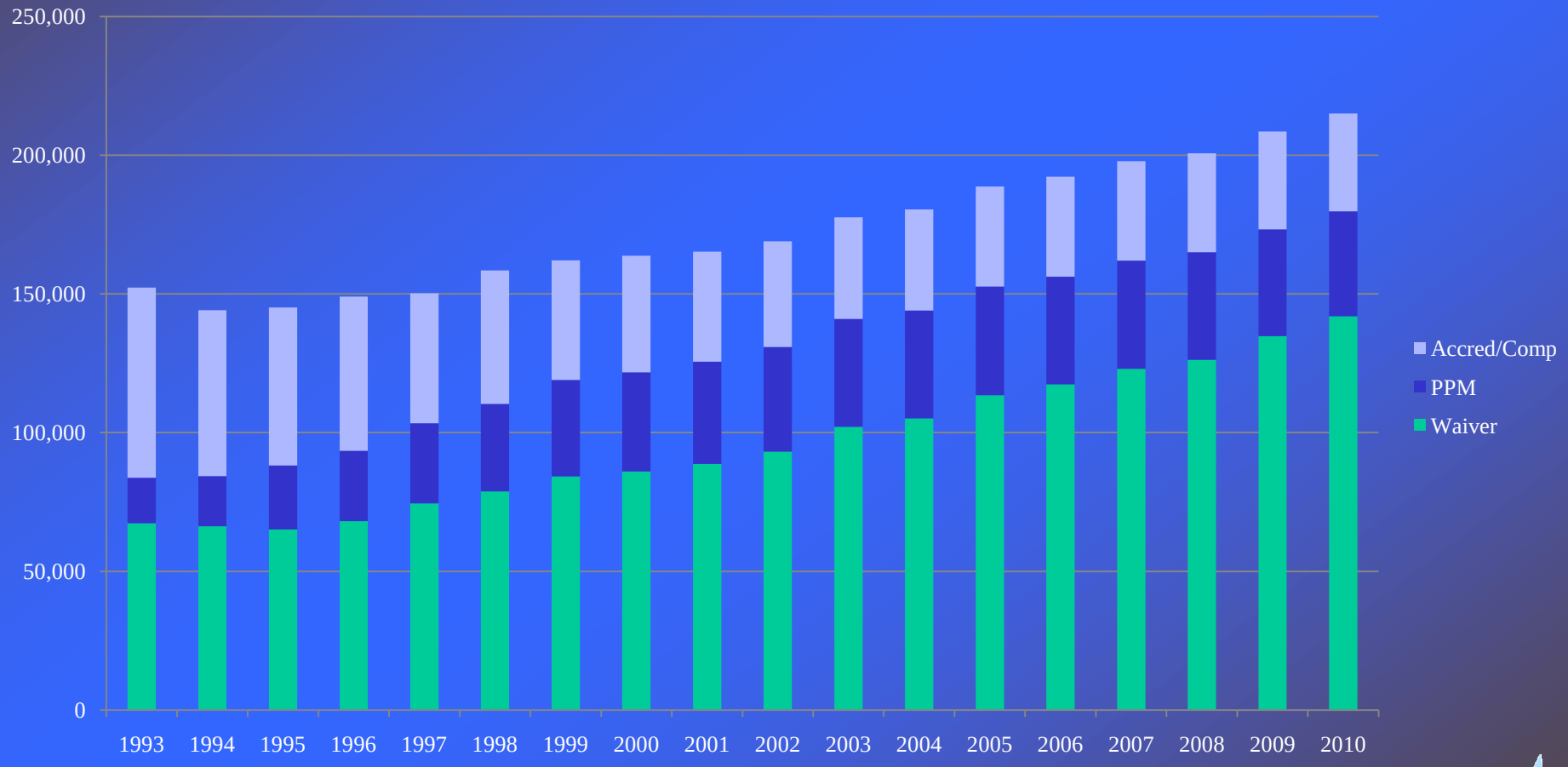


Quality System Essentials

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

CMS CLIA DATA UPDATE
Waived Lab Growth



CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

CMS/CLIAContact Information

- **CMS/CLIA web site:**

http://www.cms.hhs.gov/clia/

Includes States, Regulations, Guidelines

- **CMS/CLIA Central Office:**

  410-786-3531

- **Judy Yost's Email:**

judith.yost@cms.hhs.gov

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

THE END!!

THANK YOU!!

Questions?????

CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES