CLIA Update –2012!

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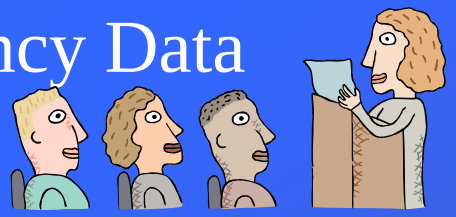
Topics for Discussion



- CLIA Statistics/CMS Survey Deficiency Data
  - Compliance Tips
- Personnel & Competency Assessment Guidance
- PT Regulation Changes & Referral Update
- CW Project Update
  - Ready, Set, Test Project
- Patient Access Rule Update
- Physician Signature Issue
- IQCP--New CLIA QC Policy Coming!
- Where to Find Info/Questions?

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Current Statistics-Enrollment

Total Number of Laboratories	**229,815**
Total Non-Exempt	**222,899**
– ***Compliance***	19,387
– ***Accredited***	15,697
– ***Waived***	150,256
– ***Provider Performed Microscopy***	37,559
– ***Exempt***	**6,802**
• *NY*	3,469
• *WA*	3,447

CMS data base 1/2012

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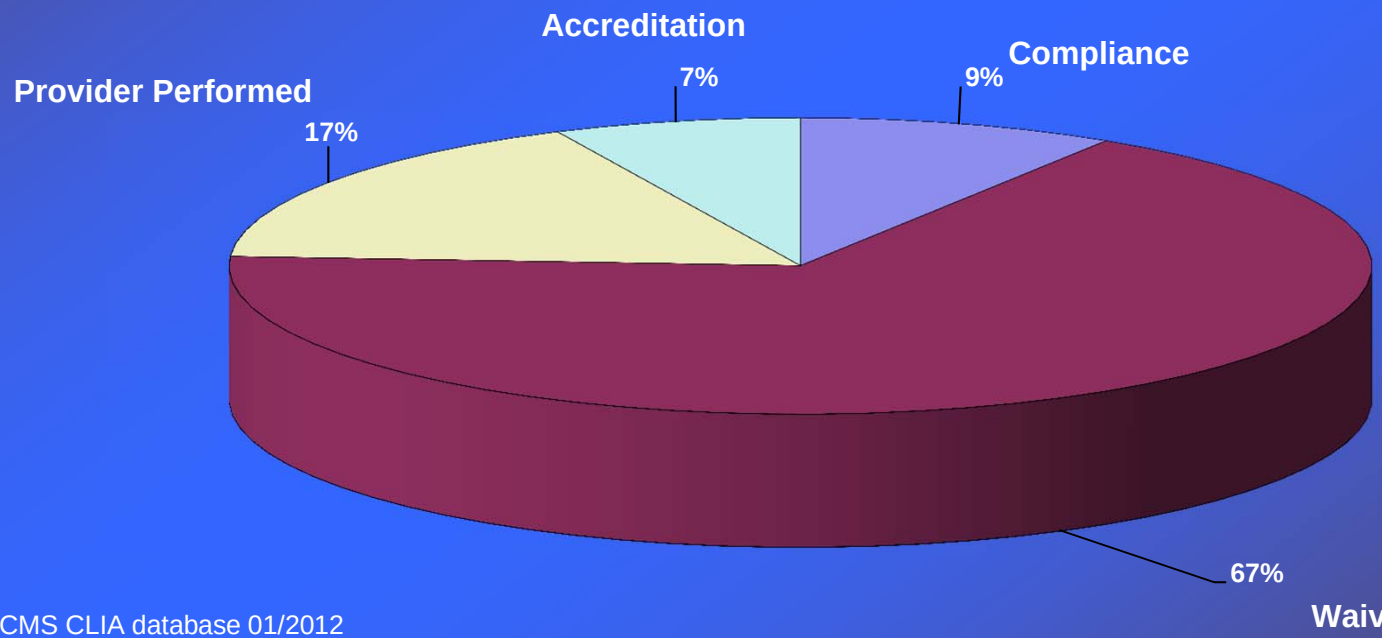
Current Statistics

CLIA Labs by Certificate Type
(Non-Exempt Only)



Source: CMS CLIA database 01/2012

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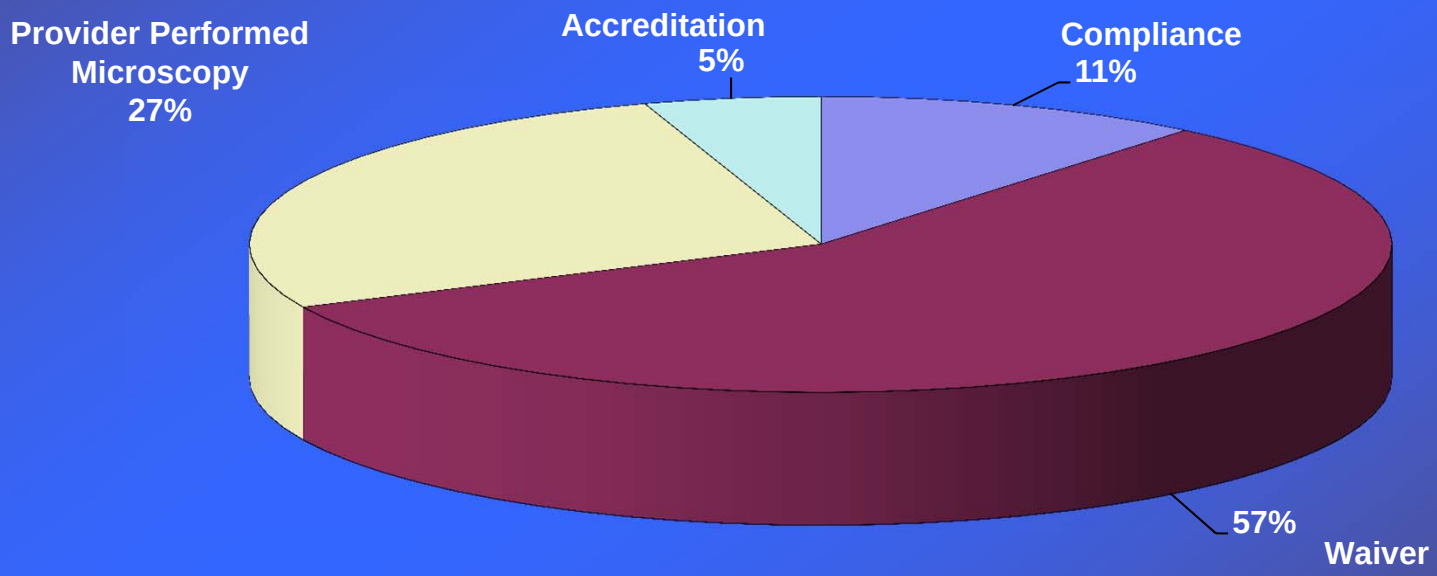
Current Statistics

Physician Office Laboratories by CLIA Certificate Type

(Non-Exempt Only)



Source: CMS CLIA database 01/2012

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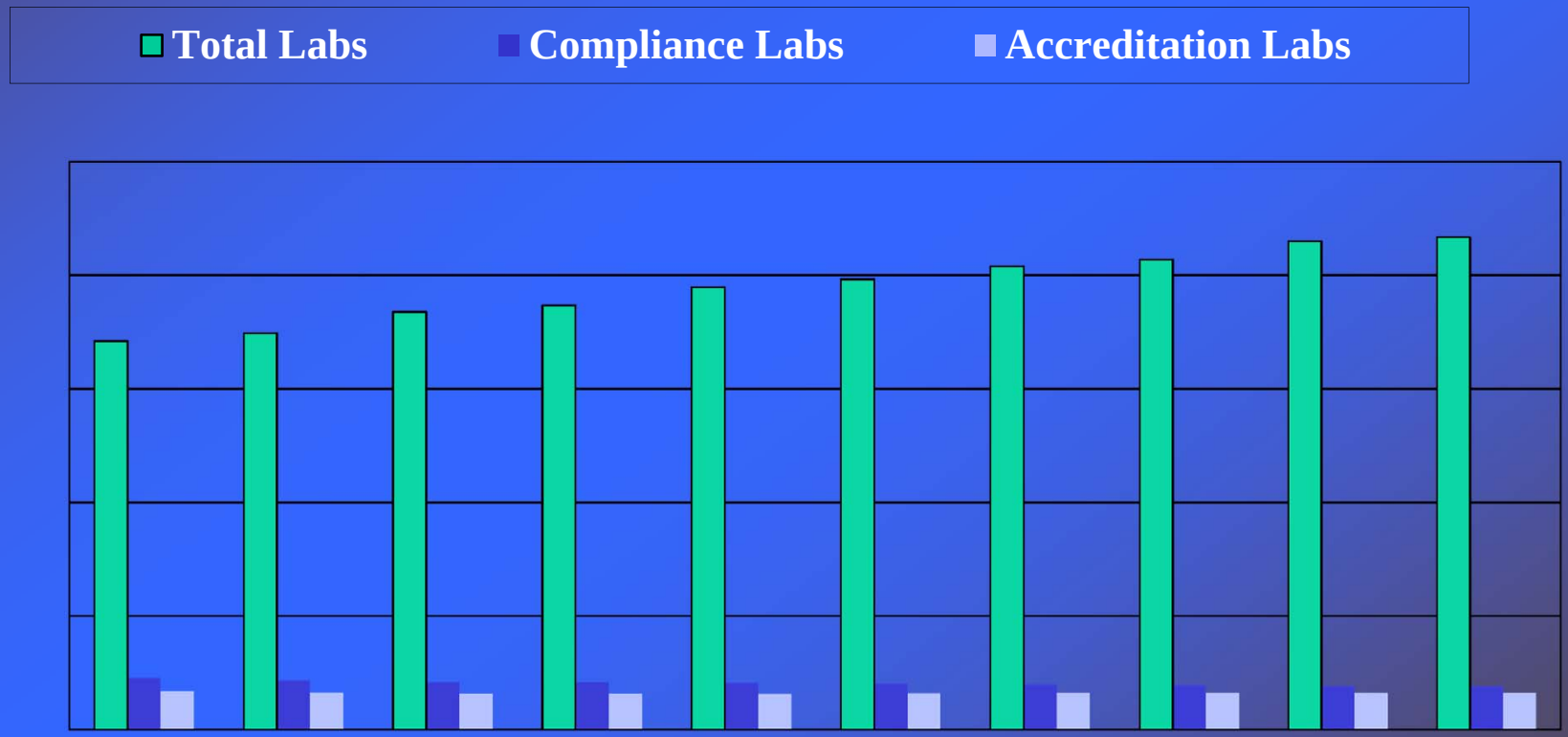
CLIA Update - General

Decade Trend



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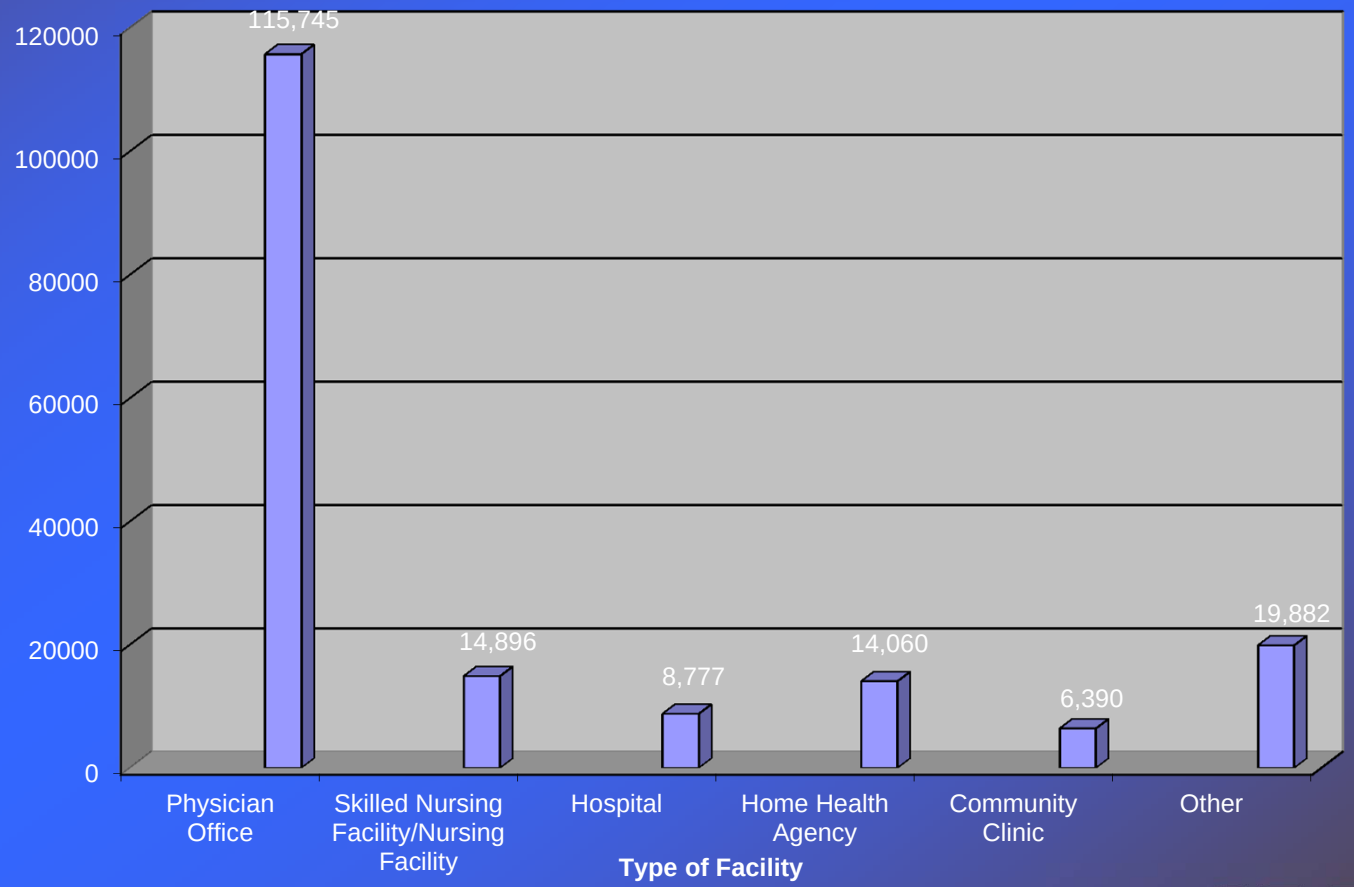
Current Statistics

CLIA Laboratory Registration
Self-Selected Laboratory Types



Source: CMS CLIA database 01/2012

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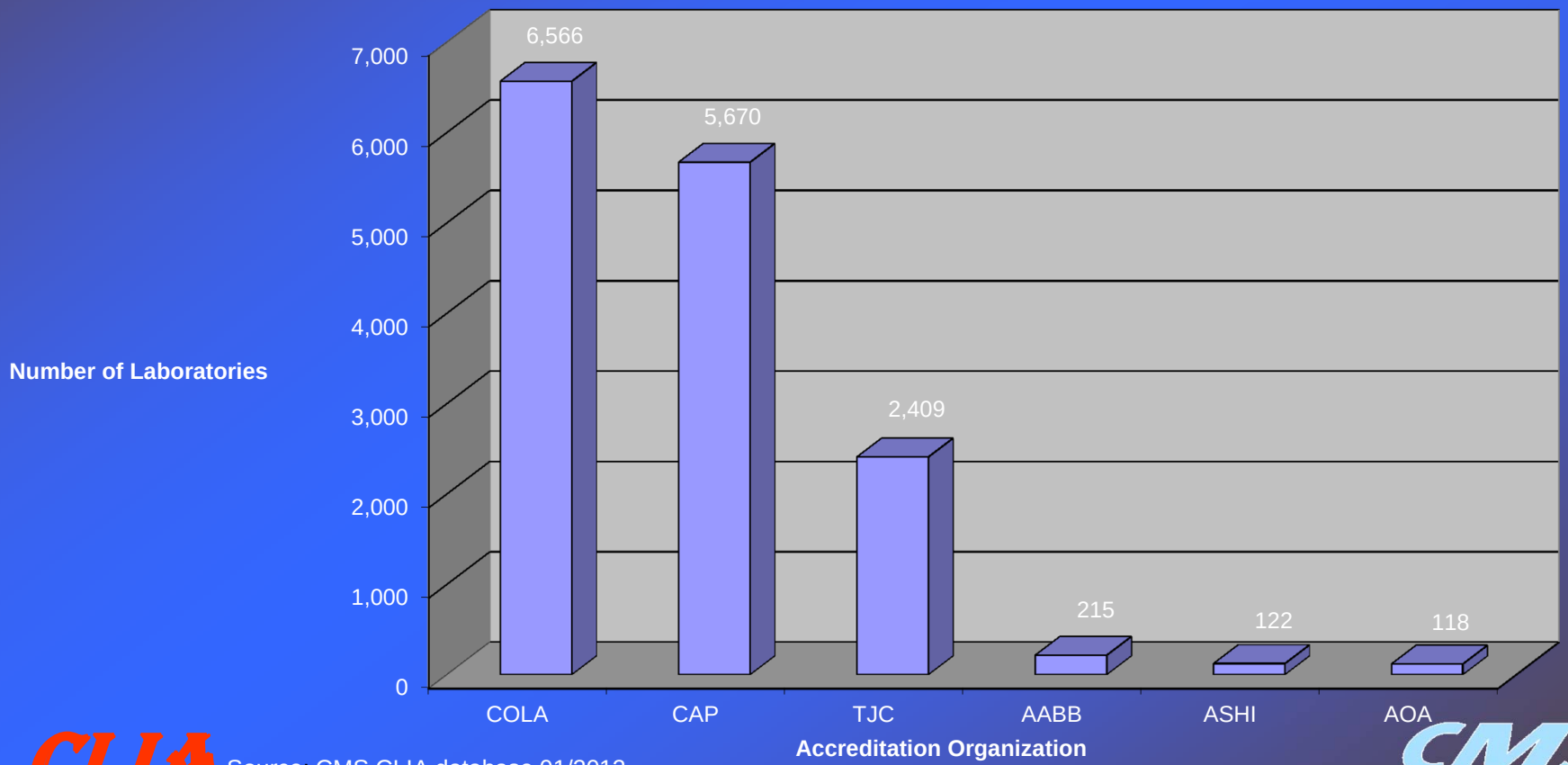
Current Statistics

Number of CLIA Certificate of Accreditation Laboratories by Accreditation Organization



CLIA Source: CMS CLIA database 01/2012

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Future of CLIA & EHR's Proposed Patient Access Rule

- Standards, practices & technology for electronic exchange of lab information are still evolving.
- CMS will revisit CLIA Interpretive Guidelines, to ensure laboratories & stakeholders have clear guidance on best practices/resources to implement Health Information Technology.
- Proposed rule for patient access to laboratory results was published 9/12/11by CMS, CDC & OCR. Comments analyzed & responses drafted for final.

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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.hhs.gov/ocr/privacy/hipaa/administrative/breachnotificationrule/postedbreaches.html
- **FDA Safety Portal**
  - https://www.safetyreporting.hhs.gov

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CLIA Personnel & Competency Policies

Topics for Discussion

- CLIA Personnel Policies
- Rationale for Policies
- Outcomes
- Goal of Discussion
- Competency Assessment

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CLIA Personnel Policies

- Use CMS Interpretive Guidelines (IG) & S & C Letter 10-07-07-CLIA as a guide
- Qualification evaluations are done @ highest level of academic achievement for the position
- All required positions & a sample of TP are reviewed ***once***.
  - Review add'l. TP on subsequent surveys along w/ any changes or new personnel
  - If a LD changes, quals. are reviewed by the appropriate AO/SA upon notification prior to approval.
  - LD responsibilities correspond to all quality standards

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CLIA Personnel Policies

- Phlebotomists, micro plating personnel, clerks, reagent & specimen prep, etc. who do not test are NOT reviewed.
- Documentation must be available w/in 1 wk. of the survey.
- MT(ASCP) & nursing licenses alone aren't acceptable.
- Even if certification is required by CLIA; e.g., CT, degrees & transcripts, etc. are still required.
- If a State license is required by CLIA, it alone is acceptable. Most States do an extensive review.
- Surveyor may still request documentation.

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CLIA Personnel Policies

- Consider test complexity when evaluating creds.
- Agency evaluations aren't acceptable, except for foreign credentialing equivalency purposes.
- Foreign educated individuals must be evaluated by a nationally recognized agency for equivalency.
- If an individual doesn't meet edu., training or experience requirements, position not filled or responsibilities not met, a condition level deficiency is cited.
- Competency is assessed per the regulations for TC/TS. Solo practitioners are not assessed.

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CLIA Personnel Policies

Rationale:

- Individuals downloaded quals. from the Web, used them fraudulently to obtain CLIA certificates & billed Medicare for mllions of $$.
- Number of false apps recorded thus far: >100!!
- Many shell labs caught by pre-approval review of application credentials.
- ASCP discovered individuals who submitted false creds. for their certification. Has changed its credentialing process.

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CLIA Personnel Policies

Rationale:

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- There is great risk to CLIA & patients if an individual in a regulated position is ID as unqualified & quality issues are also found.
- Lab w/ multiple, consecutive PT failures had TP w/ falsified HEW card. All lab results had to be reviewed.
- VA discovered falsified degrees.

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CLIA Personnel Policies

Rationale:

- Offshore operation upgrades degrees for a fee; diploma mills; quickie degrees.
- TP not following mfgr's. instructions for intended use (endocervical) testing males for GC/Chlamydia only has 10th grade edu.
- Lab w/ all personnel unqualified for high complexity micro testing it performed.

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CLIA Personnel Policies

Rationale:

- **IJ** in lab where GS had no foreign equivalency done.
- TP w/ no HS degreeor GED – test results impacted.
- POL w/ repeated deficiencies w/ MDs son who has no HS degree performing testing.

- Etc., etc., etc.

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CLIA Personnel Policies

GOALS:

1. **All oversight agencies have & enforce consistent personnel policies.**
2. **Patients are protected by qualified personnel at all levels.**

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CLIA Competency Assessment

- 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.
- Quality management includes personnel, processes, & procedures, as does competency.

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CLIA Competency Assessment

- Studies indicate that more education & training produce higher quality results.
- The means to confirm training effectiveness is competency evaluation.
- In CLIA, laboratory director's qualifications are stringent due to overall quality responsibility.
- But qualifications for testing personnel are minimal, based on test complexity.

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CLIA Competency Assessment

- CLIA survey experience indicates many problems caused by personnel errors; may have a patient impact.
- Routine competency evaluations help prevent errors; highlight importance of competency, regardless of education.

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CLIA Competency Assessment- Key Requirement

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.*

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CLIA Competency Assessment

Competency for all tests performed must include:

- *1.* ***Direct observation of routine patient test performance, including patient preparation, if applicable, specimen handling, processing & testing.***

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CLIA Competency Assessment

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

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CLIA Competency Assessment

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

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CLIA Competency Assessment

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

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CLIA Competency Assessment

- 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***

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CLIA Competency Assessment

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

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CLIA Competency Assessment Tips

- Operator training prior to testing is critical & required
- Competency assessments must be documented
- Individual conducting competency assessments must be qualified (TS/GS or TC)
- Competency is not PT! PT can be used to meet some elements of competency, but not all!
- Pathologists should be evaluated by the laboratory director as technical supervisors.
- If a service contract present, review of records is ok.

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CLIA Competency Assessment Tips

- 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.
- Competency for clinical & technical consultants & supervisors is based on their regulatory responsibilities.
- Laboratory director not subject to competency requirements, but is accountable. Responsibilities checked on surveys.
- Do not have to do all at one time; can combine elements.
- Can often combine analytes on multichannel analyzers.

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CLIA Competency Assessment Tips

- 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 evaluations must be done for Provider Performed Microscopy (PPM) individuals.
- Personnel performing pre & post analytic activities & not in regulatory positions not subject to competency, but it's good QA.

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CMS' Top 10 Condition Level Deficiencies

Citation	% Labs Cited
-Mod. complexity LD qualif./respons.	3.8%
-Successful PT participation	3.0%
-PT enrollment	1.7%
-Analytic Systems (QC)	1.4%
-High complexity director qualif./respons.	1.4%

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CMS' Top 10 Condition Level Deficiencies

Citation	% Labs Cited
Mod. complexity TP	1.2%
-Technical consultant qualif./respons-.	0.8%
-Hematology	0.6%
-High complexity TP	0.3%
-Gen. Lab Systems preanalytic	0.3%

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CMS' Top 10 Deficiencies

Citation **% Labs Cited**

- Policy for proper reagent storage---------—5.3%
- Analytic Systems' QA----------5.1%
- Verify accuracy non-PT'd tests----------—5.0%
- Follow mfgr's. instructions----------4.4%
- Procedure manual----------4.4%

Source CMS CLIA database 2/2012

CMS' Top 10 Deficiencies

Citation **% Labs Cited**

- Calibration verif.----------4.2%
- LD responsibility-QA plan----------3.9%
- Mod. complexity LD qualif./respons.---------3.8%
- Gen lab systems QA----------3.7%
- Use of expired reagents----------3.7%

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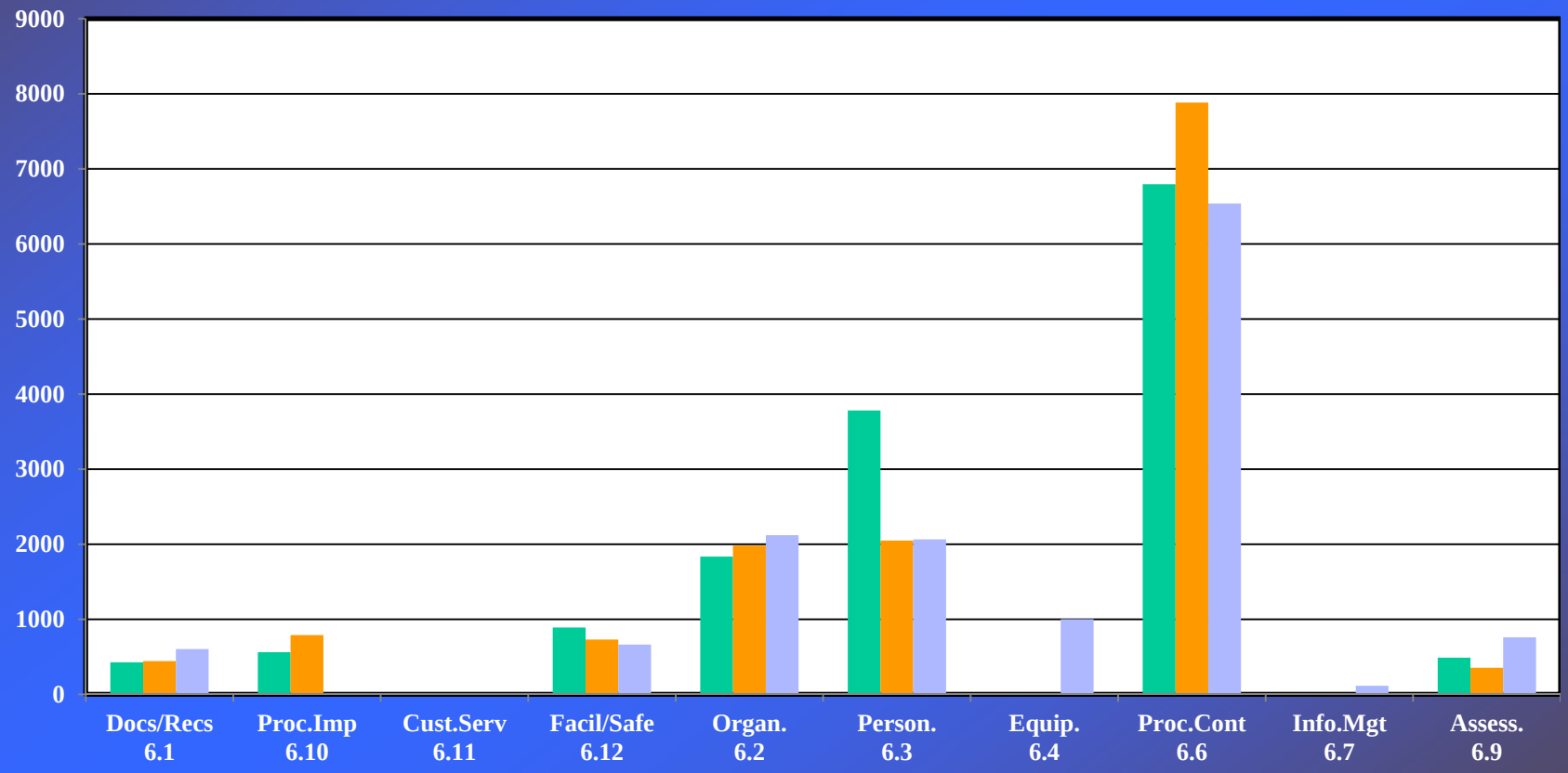
Partners' Deficiencies 2007-9



Quality System Essentials

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PT Regulation Update-1

- Plan w/ milestones & timeline developed
  - Includes: test selection, target values, grading criteria, PT programs, labs, PT referral
  - Requires a proposed rule w/ comment & final
  - No firm ETA
- CLIAC recommended to proceed
  - 1st PT providers' meeting held; 2nd Mar. 2012
  - CLIAC WG w/ SMEs from affected parties

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PT Regulation Update-2

- Ongoing work w/ CDC & CMS
- Medicare & lab data reviewed for test frequency
- Evaluated clinical uses & mechanisms to select analytes
- CLIAC WG meeting convened
- WG reported to full CLIAC; Some recommendations rec'd.
- Additional data necessary for determination of grading criteria & target values

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PT Referral Update

DO NOT SEND PT SAMPLES TO ANOTHER LABORATORY!!

- CMS Central Office continues to review all cases
- Reflex, confirmation, distributed, referral testing seem to be major causes
- Common personnel across several laboratories/health systems contribute
- Guidance--
  - For Now: Read & Follow CMS PT Brochure
  - For Future: Expect regulatory changes

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CMS QC for the Future
IQCP—The 'Right" QC!

- 2003 regulations allow use of alternative QC policy in Interpretive Guidelines (IG)
  - With equivalent quality testing
- 2004 EQC introduced; rec'd. criticism
- CMS partnered w/ CLSI to develop new guidance
- Project chaired by James Nichols. PhD.
  - CLSI convened expert team
- Doc published Oct., 2011: EP-23 "Laboratory QC by Risk Management Principles"

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CMS QC for the Future
IQCP—The 'Right" QC!

- CMS will include key concepts of EP-23 in new QC policy in IG
- Permits individualized QC plans (IQCP) for ea. laboratory/test
- IQCP is based on patient population, environment, clinical use, test system, etc.
- Uses much of lab's existing quality practices/data
- Includes current & new tests; exc. pathology
- May not decrease QC, but is the "right " QC

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CMS QC for the Future
IQCP—The "Right" QC!

- New QC is voluntary & applicable to CMS certified non-waived abs; new & existing tests
- Default is 2 levels of external QC/day
- Education/transition period-no citations; begin planning!
- Training & guidance will be available for surveyors & labs
- Once effective, deficiencies cited; EQC sunsets
- No regulation or survey process changes
- Accredited labs meet AO standards, until otherwise notified

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Waived Testing Project

- Waived tests offer timely, efficient, convenient patient care
- Continue to increase (ex. 300 pharmacies in 1995 to 6,000 now!)
- Increased testing comes w/ issues:
  - ✓ Testing personnel less-trained; may not ID problems
  - ✓ No routine oversight w/ no funding/resources
  - ✓ Minimal mfr. required QC=quality issues
  - ✓ Pre & post analytical issues

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CMS Waived Project

Since 1992……

- CLIA-waived tests increased from 8 to ~100 tests.
  - **This represents 1000's of test systems!**
- The number of laboratories issued a CW has grown exponentially from 20% to 67% of >230,000 laboratories enrolled.
- The only standard for CW laboratories is to ***follow manufacturer's instructions*** & register w/ CMS.

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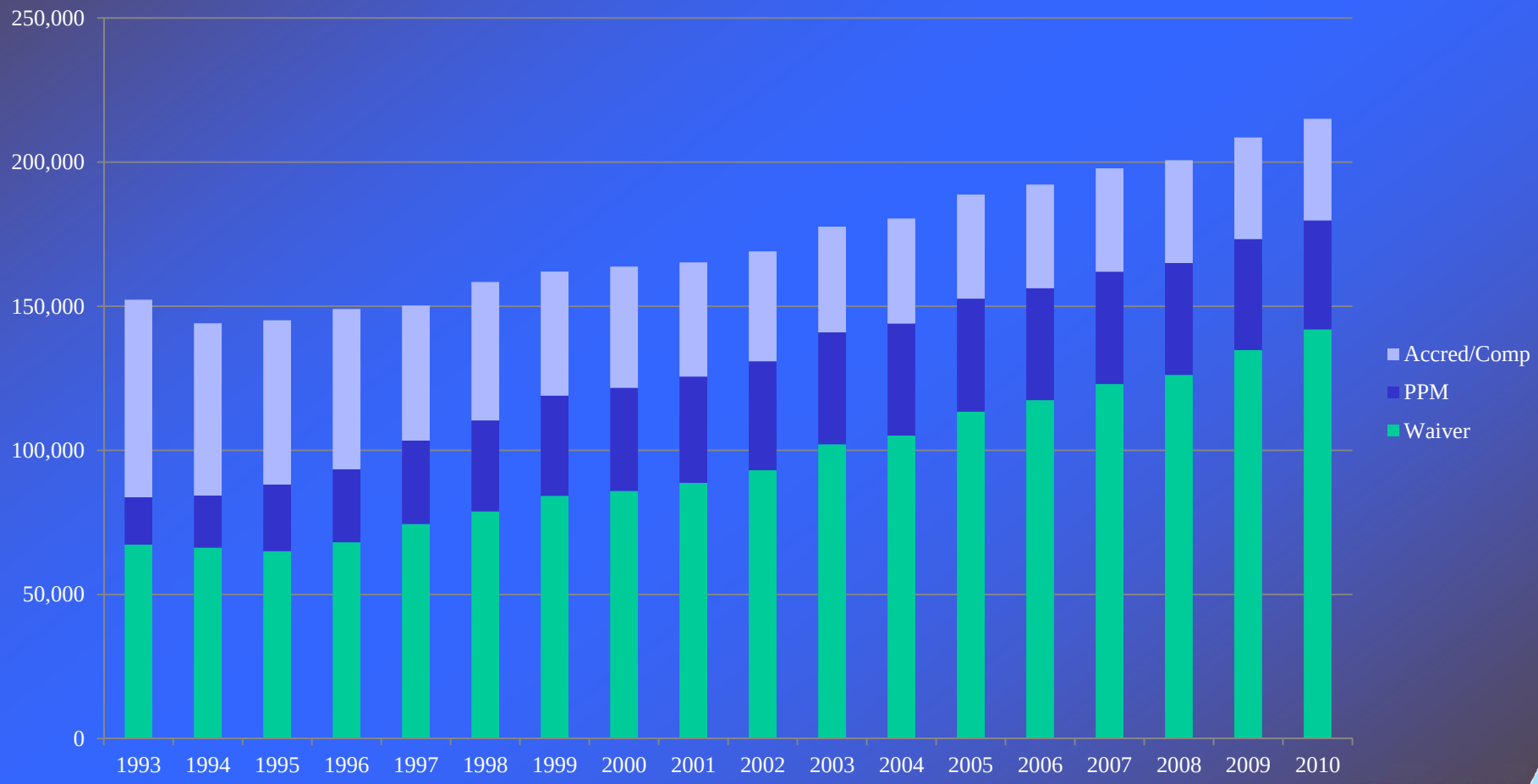
CMS Waived Project --Waived Laboratory Growth



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CMS Waived Project Beginnings

- In 1999 CO & OH visited 100 CW & laboratories; **50% had quality problems**!
- As a result, CMS expanded the pilot to the 8 other States.
- That data demonstrated the need for a national & ongoing project.

A 2% sample of CW labs is visited annually by CMS; each CW lab responds to standard questions about its waived testing practices.

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CMS Waived Project Findings

CDC & CMS Found Then & Now:

- High staff turnover in waived testing sites
- Lack of formal laboratory education
- Limited training in test performance & QA
- Lack of awareness concerning “good laboratory practice”
- Partial compliance with manufacturers’ QC instructions (~55-60%)
- NY studies correspond to CMS’

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CMS Waived Project- 2006 & Ongoing

2006 Initial visits

Of 1947 labs visited, 69% were following the manufacturer's instructions.

2006 Follow-up visits Of 414 labs revisited for not following manufacturer's instructions, 353 or ***85% improved upon revisit.***

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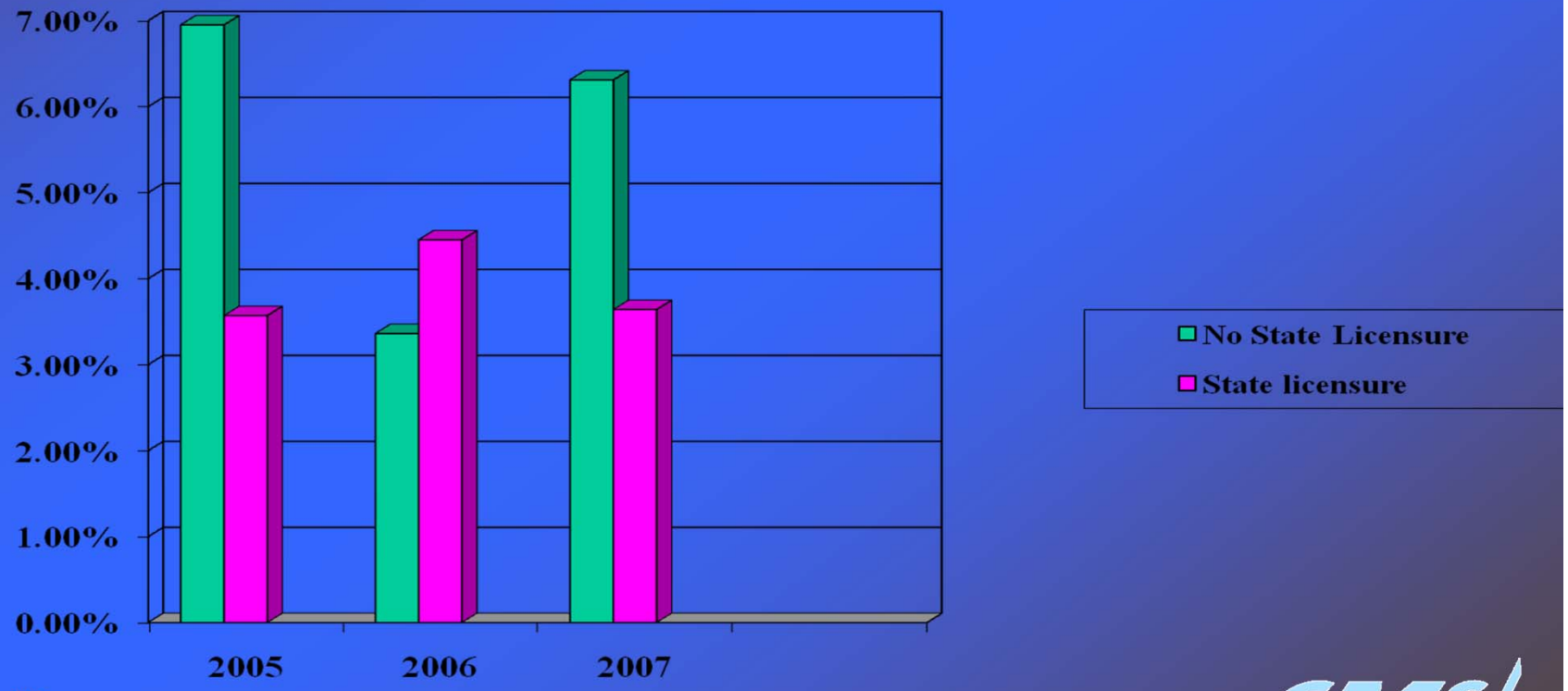
CMS Waived Project- % Performing Non-Waived Tests



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CMS Waived Project—
Immediate Jeopardy Cases!!

- FY 2005: 6 out of 1678 surveys or <1%
- FY 2006: 6 out of 1938 surveys or <0.5%
- FY 2007: 2 out of 1737 surveys or <0.20%
- FY 2008: 3 out of 1902 surveys or <0.16%

Consider if you extrapolate these data to the total CW lab population!

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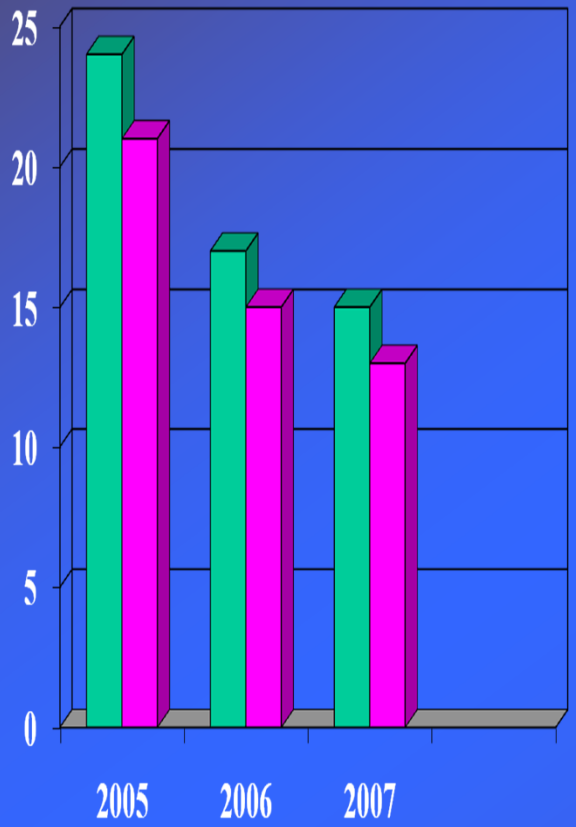
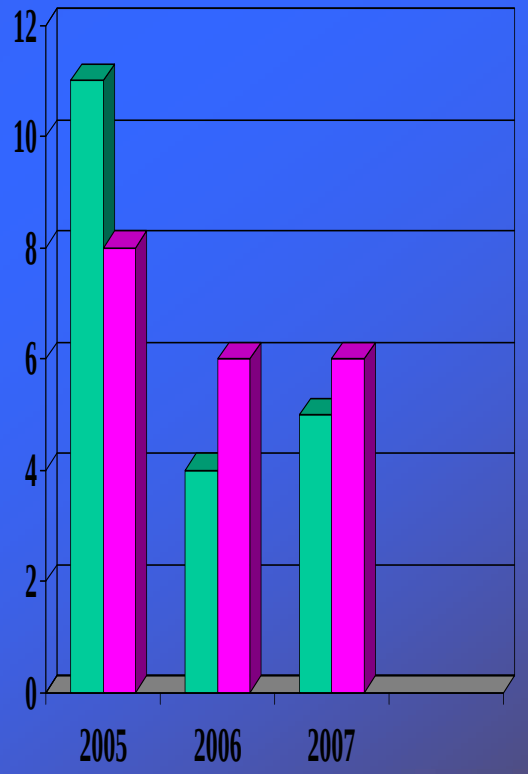
CMS Waived Project- Not Doing Required QC 1st & 2nd Visits Compared





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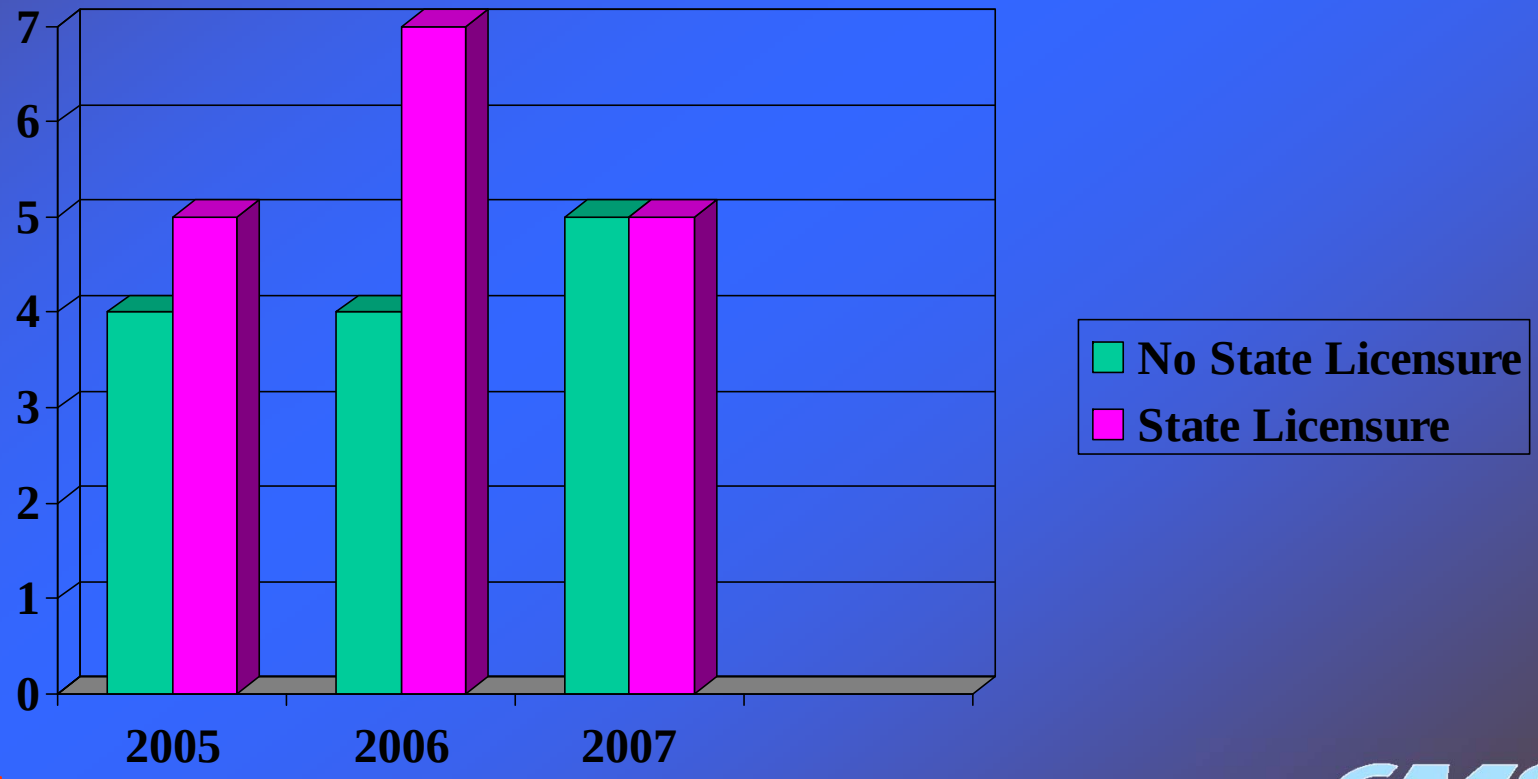
CMS Waived Project-% w/ Voluntary Proficiency Testing



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CMS Waived Project- Performance w/ Voluntary P T

CW Survey Response	PT	No PT
Lab has current mfgr's. instructions	98%	88%
Performs required QC	95%	75%
Performs req'd function chks/calibrat	75%	62%
Performs confirmatory testing	25%	15%

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CMS' Plans for Waived Project

Short term

- Continue CW project indefinitely
- Provide edu. materials w/ ea. new app, on web site, w/ on-site visits; update CE clearinghouse
- Initiate test menu collection w/ apps
- Collaborate w/ stakeholders, CDC to ID add'l. efforts
- Evaluate data from AO/ES w/ CW standards
- Coordinate w/ FDA on overlapping issues
- Publish comprehensive report
- Ask me about new pilot project: Ready, Set, Test!

Long term-Change the CLIA law to enhance oversight

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CMS & CDC's 'Ready, Set, Test!' Waived Lab Project

- CDC, w/ CMS input, designed an educational booklet entitled 'Ready, Set, Test!' for CW labs
- CMS will send booklet to a small sample of waived labs prior to visit
- CMS will evaluate labs' performance vs those which received no booklets
- Data will be a CLIA performance measure
- If successful, will share w/ all waived labs

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Physician Signature on Test Requisition

- Physician signature required on paper laboratory test requisitions under the CY2011 Physician Fee Schedule proposed rule
- CMS issued memorandum March 31, 2011 notifying Medicare contractors not to enforce the requirement for physician signature
- For remainder of 2011, CMS changed the regulation requiring physician signature

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CLIA 20 Year Anniversary!!
1992-2012

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For More Information

CMS CLIA Web Site:

www.cms.hhs.gov/clia/

brochures, guidance, lab demographics, app, contacts

CMS CLIA Program

410-786-3531

Judy Yost's Email:

Judith.yost@cms.hhs.gov

IQCP Link

IQCP@cms.hhs.gov

My gratitude to Karen Dyer, Daralyn Hassan & Cindy Flacks for their contributions.

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THE END!!

Thank you!

Questions??

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