CMS CLIA Update 2010

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CLIA Update

CMS Potpourri:

- Current CMS CLIA Statistics
- Cytology PT NPRM
- CMS Top Survey Deficiencies
- CMS Enforcement Data
- CLSI EP-23: Alternative QC for Laboratories
- Transfusion Fatality Investigations
- PT Regulation Update Plan
- CMS Waived Project Next Steps
- Electronic Health Records (EHR) & CLIA
- New Complaint Brochure & Complaint Data
- Personnel Policy
- Questions & Answers

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Current Statistics

- **Total Number of Laboratories: 214,875**
  - ***Compliance*** 19,178
  - ***Accredited*** 16,095
  - ***Waived*** 134,778
  - ***Provider Performed Microscopy*** 38,509

  - ***Exempt*** **6,315**
    - *NY* 3,103
    - *WA* 3,212

CMS data base 10/2009

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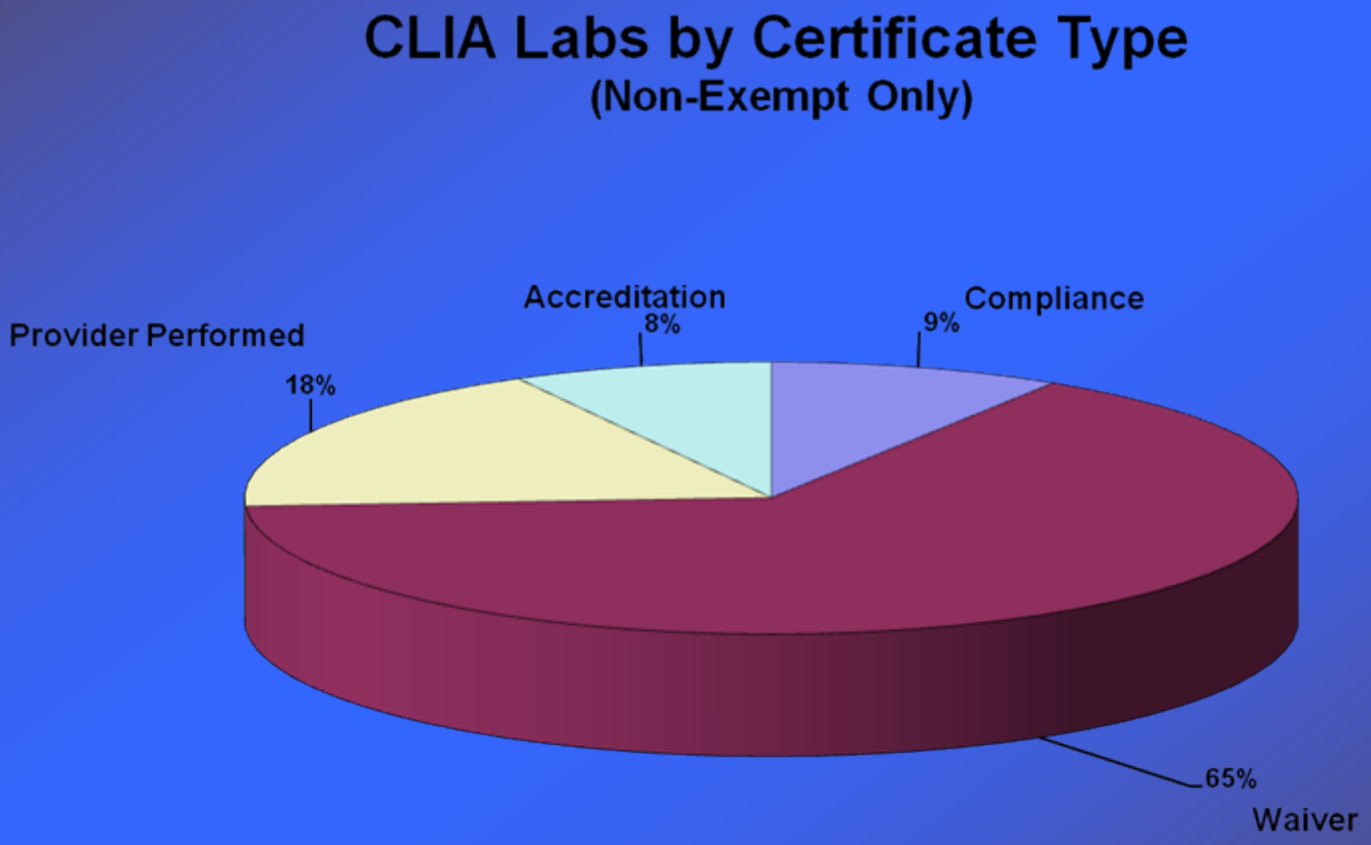
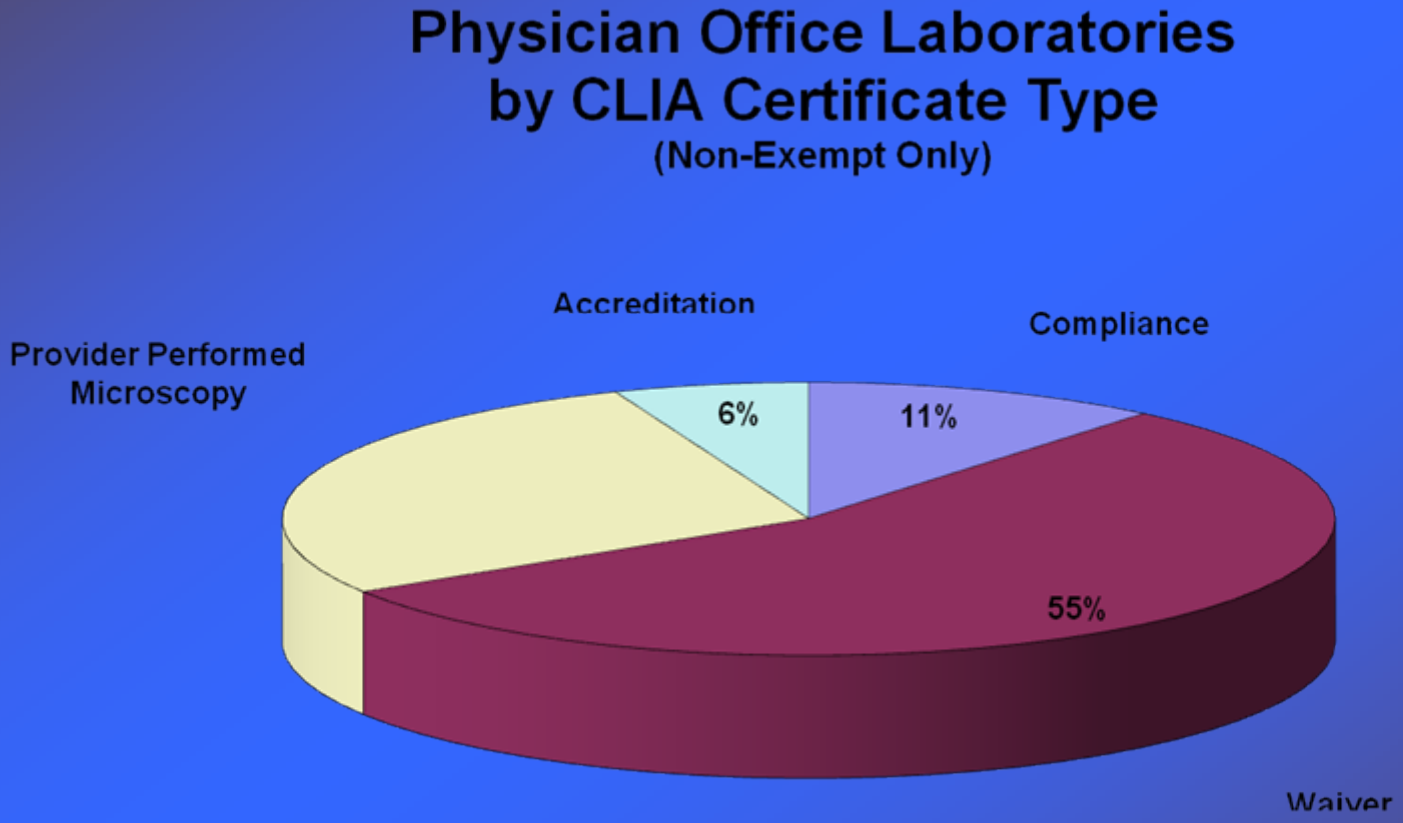
Current Statistics



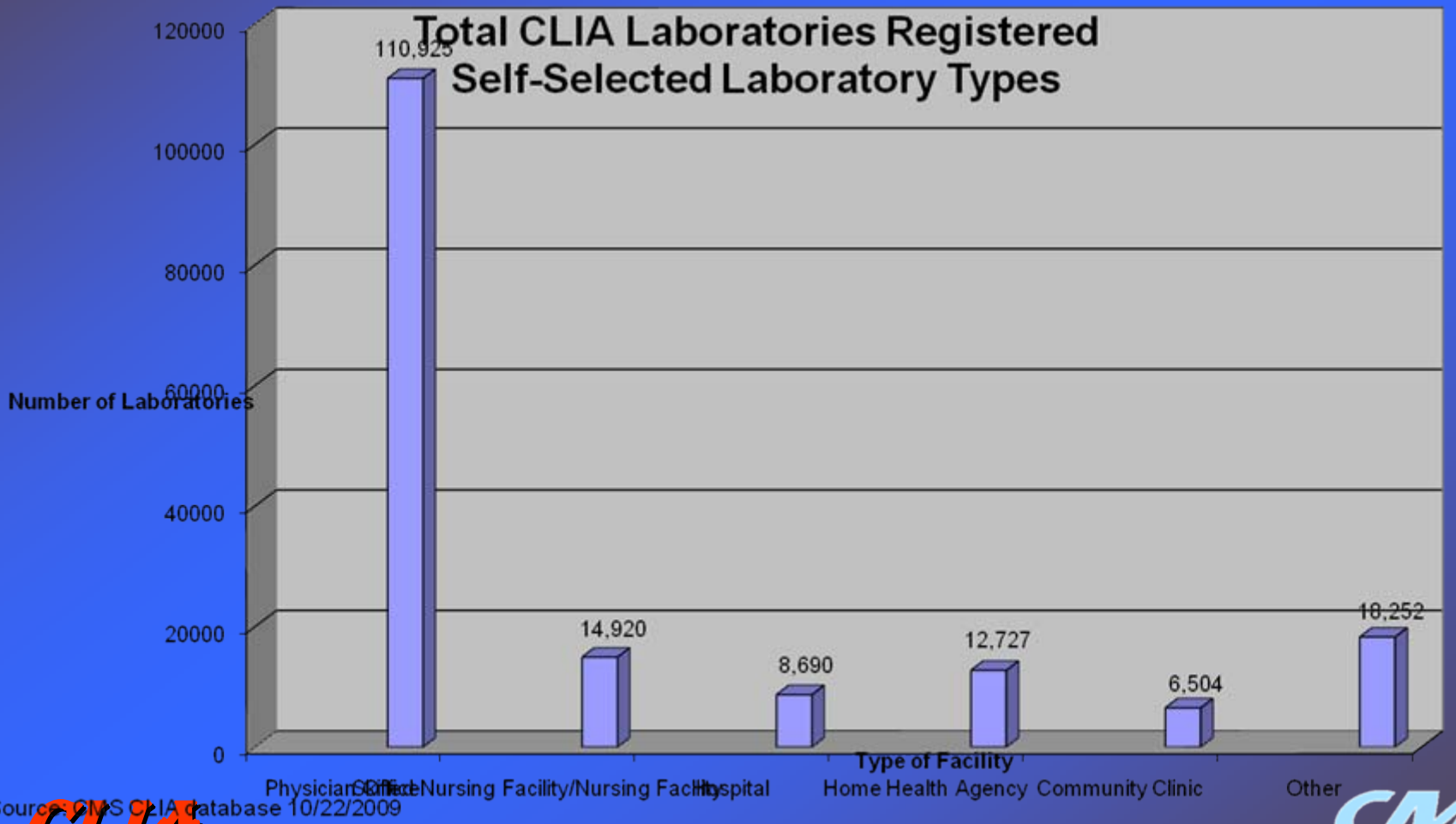
Source: CMS CLIA database 10/22/2009

Current Statistics



Source: CMS CLIA database 10/22/2009

Current Statistics



Source: CMS CLIA database 10/22/2009

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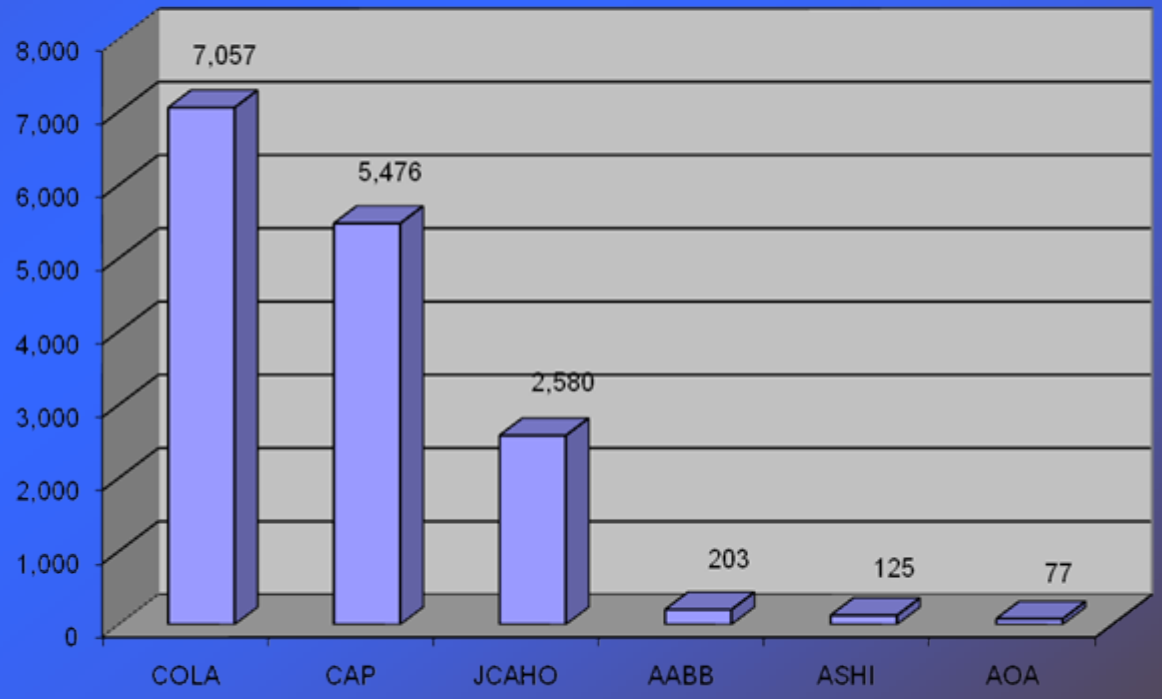
Current Statistics

Number of CLIA Certificate of Accreditation Laboratories
by Accreditation Organization



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Current Statistics

Compliance Labs by Certificate Schedule

Schedule	Annual Vol.	No. Labs
Low Vol. A	up to 2,000	7,791
A	2001-10,000	4,825
B	2001-10,000	755
C	10,001-25,000	1,692
D	10,001-25,000	595
E	25,001-50,000	1,309

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Current Statistics

Compliance Labs by Certificate Schedule

Schedule	Annual Vol.	No. Labs
F	50,001-75,000	646
G	75,001-100,000	405
H	100,001-500,000	953
I	500,001-1,000,000	104
J	>1,000,000	77
	TOTAL	**19,178 Labs**

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Cytology PT

Cytology PT Proposed Regulation:

- Proposed rule considered 17 CLIAC recommendations.
- Pub. by CMS Jan. ‘09; comments closed Mar. ‘09.
- Joint CDC/CMS collaboration.
- Contains questions; solicits comments & suggestions.
- 5,193 comments received from 660 commentors
- Comments are being analyzed
- Stay tuned!

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Cytology PT

Current Regulation	Proposed Regulation
10 Slides/Test	20 Slides/Test
2 Hours/Test	4 Hours/Test
Annual Test	Biennial Test
Test Composition:	***Test Composition***:
1 Unsatisfactory	1 Unsatisfactory
1 Normal	1 Normal
1 Low Grade (LSIL)	1 LSIL
1 High Grade (HSIL)/Cancer (CA)	2 HSIL or CA

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Cytology PT

Current Regulation	Proposed Regulation
1 Missed HSIL/CA=Auto. Fail	2 Missed HSIL or CA = Auto. Fail
Glass Slide Test Only	Glass Slide/New Tech.
Slide Field Valid. Not Req'd.	Slide Field Valid. Req'd.
Appeal Process Not Req'd.	Appeal Process Req'd.
Diff. Scoring Grids Path.& CT	Diff. Scoring Grids Path. & CT

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Cytology PT

Comparison of PT Performance, 1st Test

2005	91% passed
2006	95% passed
2007	96% passed
2008	97% passed
2009	97% Passed

Value of cytology PT:

-Identifies those who shouldn't screen.

-Demonstrates high quality of those who do.

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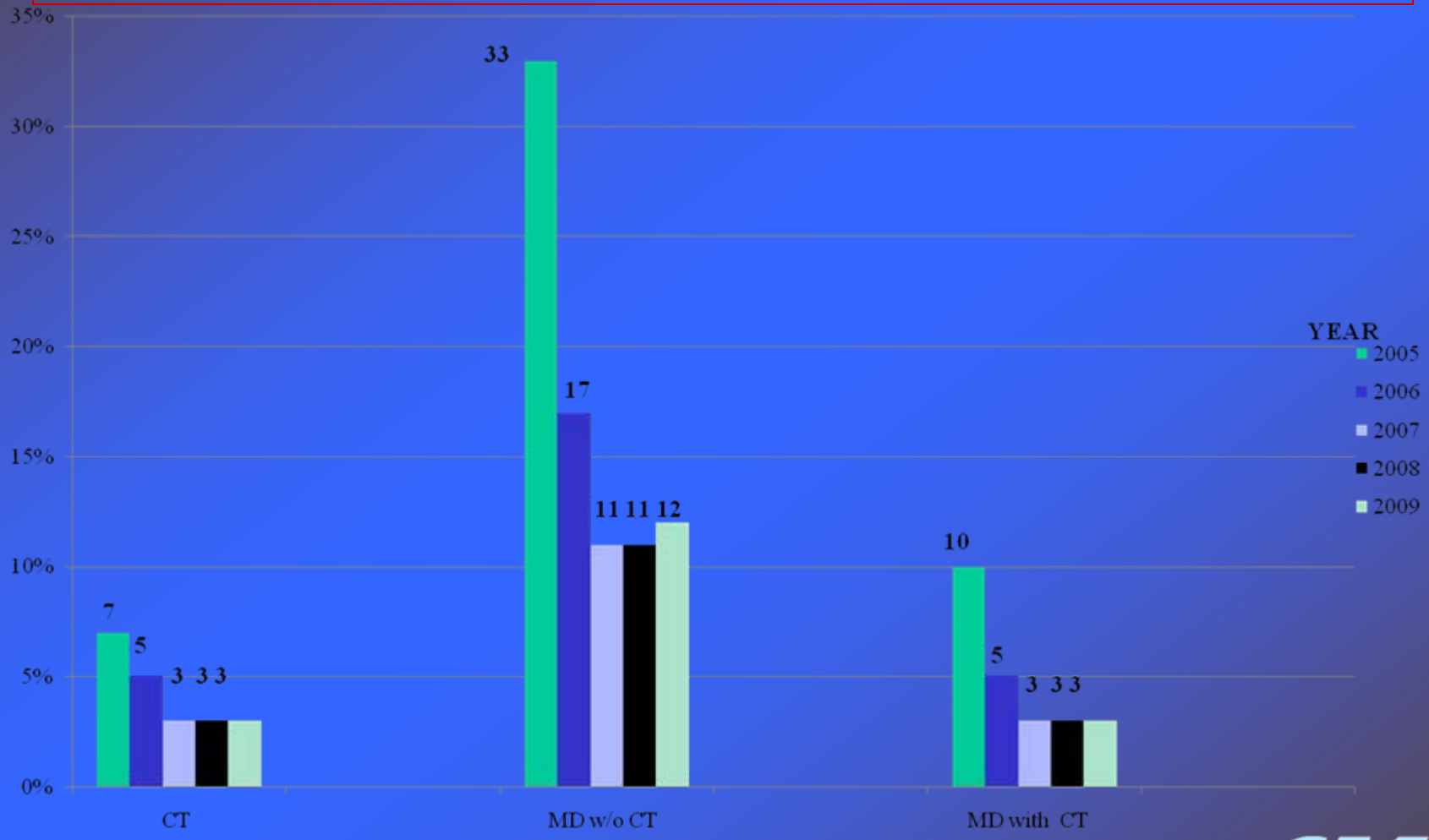
Cytology PT



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CMS' Top 10 Condition Level Deficiencies

Citation	% Labs Cited
-Mod. complexity LD qualif./respons.	4.4%
-Successful PT participation	4.1%
-PT enrollment	1.9%
-Analytic Systems (QC)	1.9%
-Mod. complexity TP	1.5%

Source: CMS CLIA Database 10/09

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CMS' Top 10 Condition Level Deficiencies

Citation **% Labs Cited**

-High complexity director qualif./respons.-------1.2%
-Technical consultant qualif./respons-.----------0.9%
-Hematology----------0.6%
-Bacteriology----------0.4%
-Gen. Lab Systems----------0.3%

CMS CLIA Database 10/09

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CMS' Top 10 Deficiencies

Citation	% Labs Cited
• Policy for proper reagent storage	6.9%
• Verify accuracy non-PT'd tests	6.3%
• Analytic Systems' QA	5.7%
• Follow mfgr's. instructions	5.1%
• Procedure manual	4.7%

Source: CMS CLIA data base 10/09
Labs surveyed: 18,169

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CMS' Top 10 Deficiencies

Citation	% Labs Cited
• LD responsibility-QA plan	4.6%
• Calibration verif.	4.4%
• Mod. complexity LD qualif./respons.	4.4%
• Use of expired reagents	4.2%
• Gen lab systems QA	4.1%

Source: CMS CLIA data base 10/09
Labs surveyed: 18,169

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CMS 2009 Enforcement Data

- ✓ ***551 labs had sanctions <u>proposed</u>***
  - ✓ *Principal---372 sanctions*
    - ✓ *Certificate limitation, suspension, revocation*
  - ✓ *Alternative---806 sanctions*
    - ✓ *DPOC, on-site monitor, CMP, T&TA, cancel /suspend Medicare*
- ✓ ***141 labs had sanctions <u>imposed</u>***
  - ✓ *Principal---76 sanctions*
  - ✓ *Alternative---183 sanctions*
  - ✓ *59 Immediate Jeopardy*

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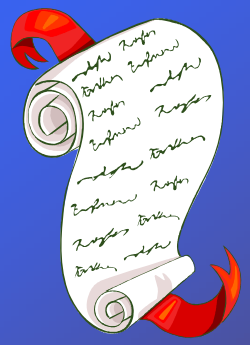
2008 Annual Lab Registry

- CLIA requires public listing of all enforcement actions
- >300 total listings for 2008 (some >1X)
  - 94 labs --certificate revoked &/or lost Medicare
    - IJ, Cond. Noncompliance, POC bad, PT referral
  - 63 labs -- certificate limited
    - Unsuccessful PT performance
  - 86 -- Directed POC
  - 14 -- CMP
  - 81 accredited labs rec'd. probation, cease testing/limitation or were denied accreditation.
- Lab types correspond to proportions of total lab pop.
  - POLs, independent, hospitals most entries



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Status Alternative QC Development-1

- '05 CLSI meeting sponsored by lab prof. orgs., gov't., industry discussed **"QC for the Future".**
  - *Labs need more info from manufacturers.*
  - *One-size-fits-all QC not good for diff. test systems/labs.*
- 2 CLSI Evaluation Protocol (EP) QC docs in development.
  - EP-23: Alternative, custom QC for labs (*Jim Nichols*)
  - EP-22: ISO risk mgt. for mfgrs. (*Greg Cooper*).
- Uses consensus process & includes all constituencies.

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Status Alternative QC Development-2

- CMS is working w/ CLSI ongoing
  - Exciting, groundbreaking efforts nearly complete!
  - AOs interested,; goal is for standard policies.
- Documents in CLSI clearance
  - Possible companion products
- Labs should begin to learn & plan now!
- Will be phased in by CMS
- CMS Interpretive Guidelines will be revised accordingly
  - Have not determined if EQC will remain

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FY 2009 Transfusion Fatality Investigations

- CMS coordinates w/ FDA Center for Biologics Evaluation & Research to investigate transfusion fatalities
- Complementary oversight requirements exist
- CMS performs investigations for CLIA & hospital deficiencies

Investigation Type	#	Facilities w/ Deficiencies
Lab	8	6
Hospital	2	1
Both	1	0

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PT Regulation Update-1

- Plan w/ milestones & timeline developed
  - Includes standards for: test selection, target values, grading criteria, PT providers, labs, PT referral, alternative assessment
  - Requires a proposed rule w/ comment & final
  - No firm ETA
- CLIAC recommendation to proceed rec'd. '08
  - CLIAC WG w/ SMEs from affected parties

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PT Regulation Update-2

- Ongoing T/C occur betw. CDC & CMS
- Medicare data reviewed for test frequency
- PT providers' meeting convened Nov.'08
- Evaluating mechanisms for analyte selection
  - Including genetic tests
- CLIAC WG meeting March 2010
- WG will report to CLIAC in Sept. 2010
- May require >1 meeting

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CMS Waived Project

- **By CLIA definition…..**

  Waived tests are;

  "…..simple laboratory examinations & procedures which –

  Employ methodologies that are so simple & accurate as to render the likelihood of erroneous results negligible;

  Pose no reasonable risk of harm to the patient if the test is performed incorrectly".

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Waived Testing

- Offers timely, efficient, convenient patient care
- Continues to increase
- 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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Since 1992……

- CLIA-waived tests have increased from 8 to about 100 tests.
  - **This represents 1000's of test systems!**
- The number of laboratories issued a CW has grown exponentially from 20% to 65% of the >214,000 laboratories enrolled.

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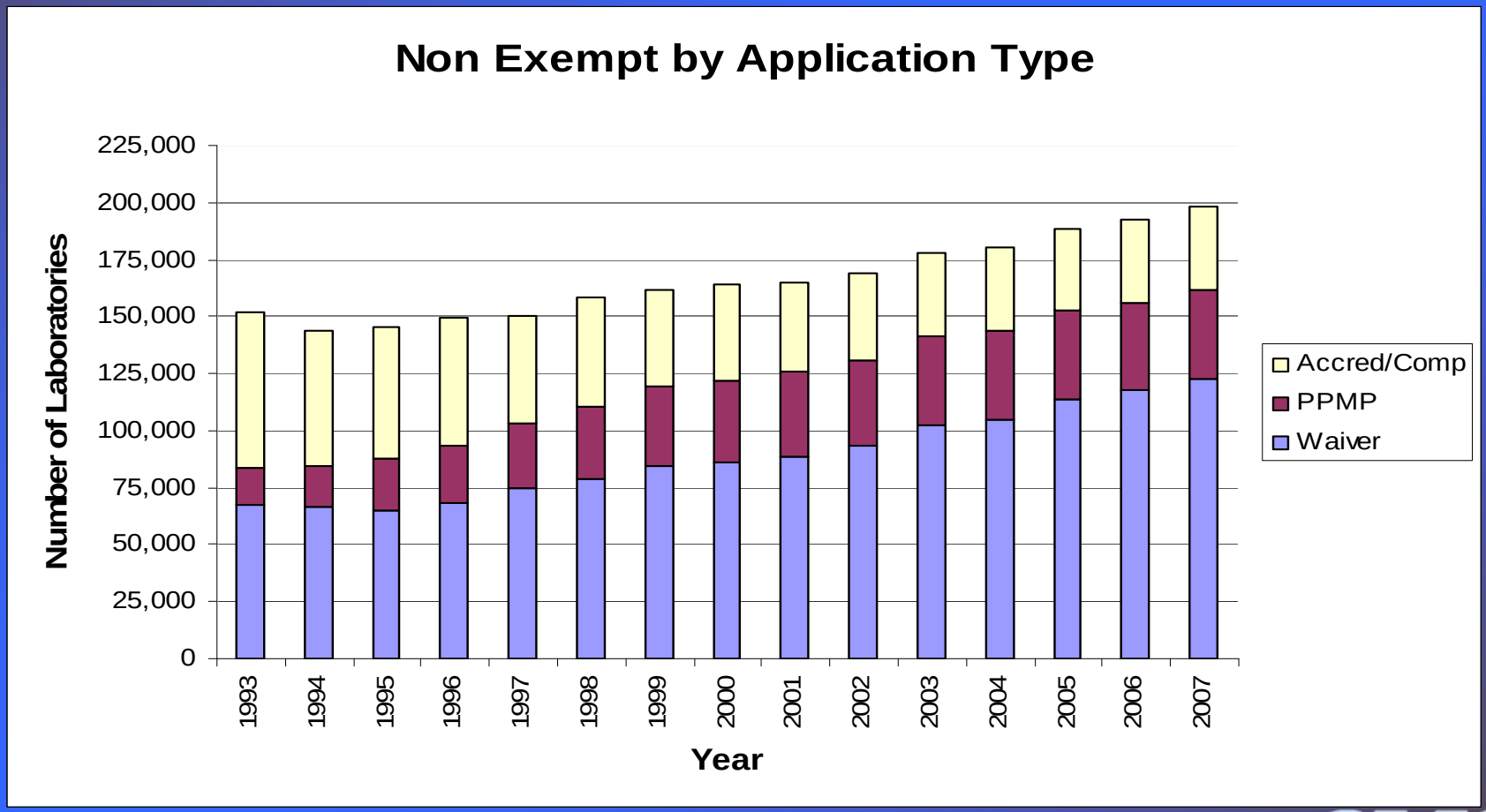
Growth of Waived Labs vs. Non-waived Labs



CMS CERTIFICATE OF WAIVER (CW) PROJECT

- The only standard for CW laboratories is to *follow manufacturer's instructions* & register w/ CMS.
- As part of the CW project, each CW laboratory visited responds to standard questions about its waived testing practices.

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CMS CERTIFICATE OF WAIVER (CW) PROJECT DATA

1999 Pilot Project:

- CO & OH each visited 100 CW & PPMP laboratories; **50% had quality problems**!

- As a result of findings in CO & OH, CMS expanded the pilot to the 8 other States.

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2004 CDC Findings Include…

- 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%)
- CDC & NY studies correspond to CMS’.

(Presentation CLIAC_Waived testing update_Sept 2004.)

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CMS CW Project Data
FY 2006

Initial visits

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

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

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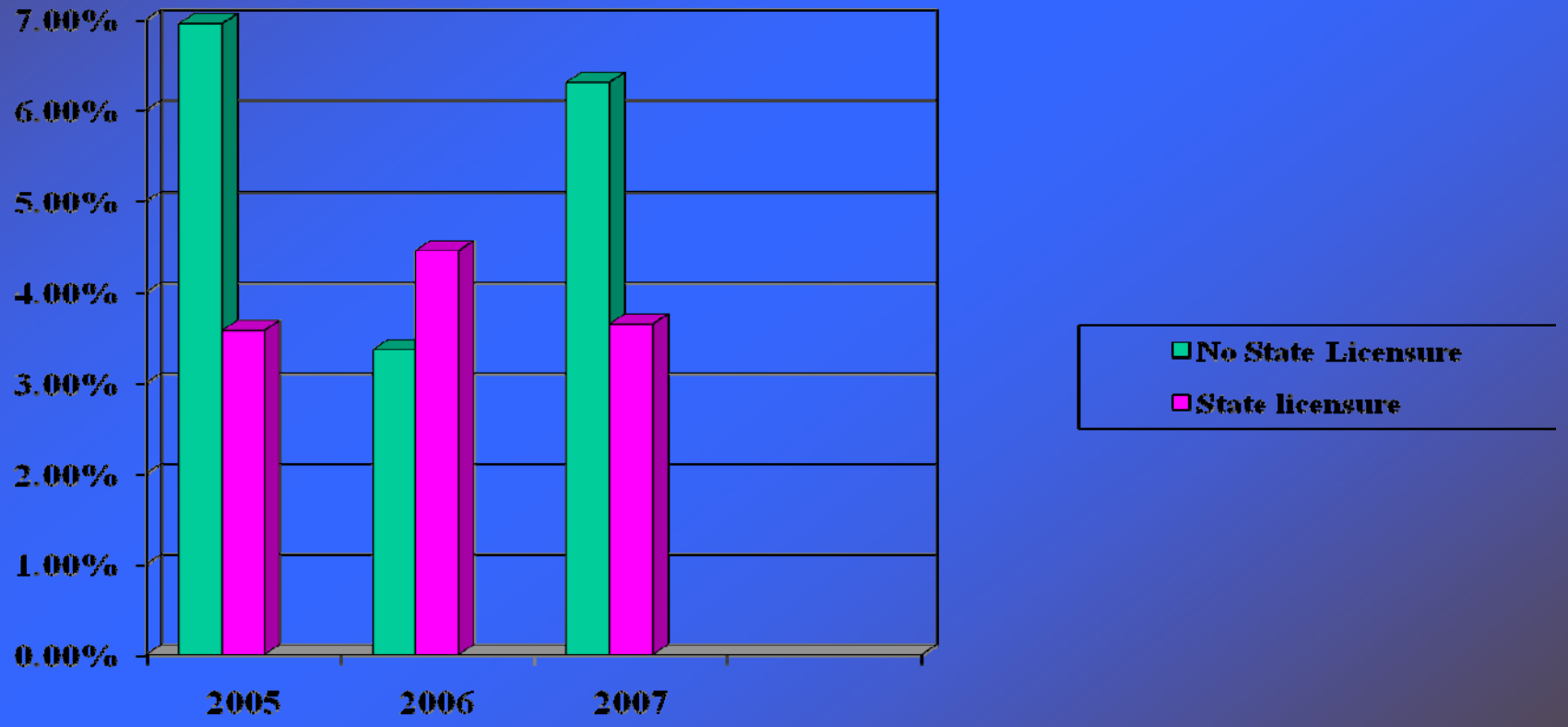
Percentage of CW Labs Performing Non-waived Tests



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CMS CW Project– IJ
Risk of Harm

- 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 nos. to the total CW population of labs!

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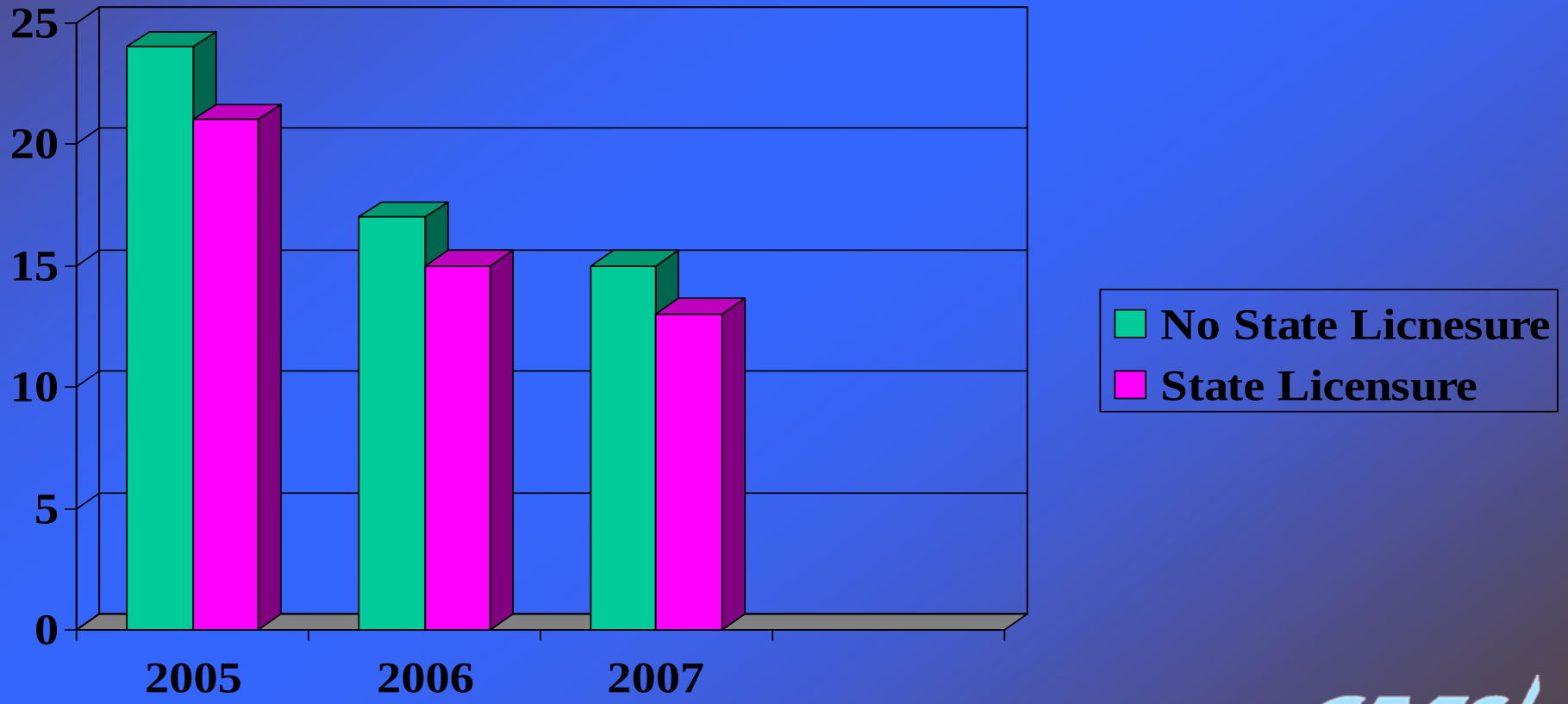
CW Labs Not Performing Required QC on Initial Visit



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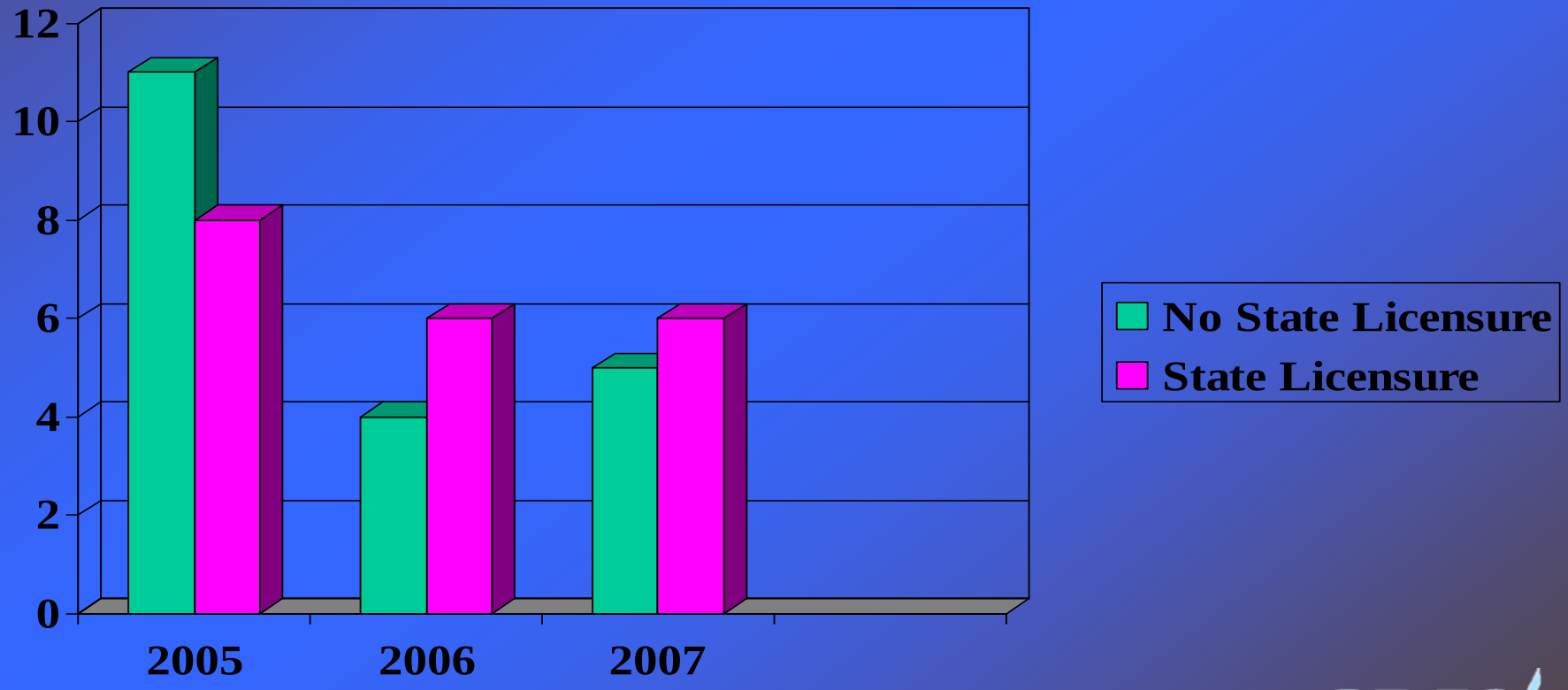
CW Labs Not Performing Required QC After Follow Up Visit



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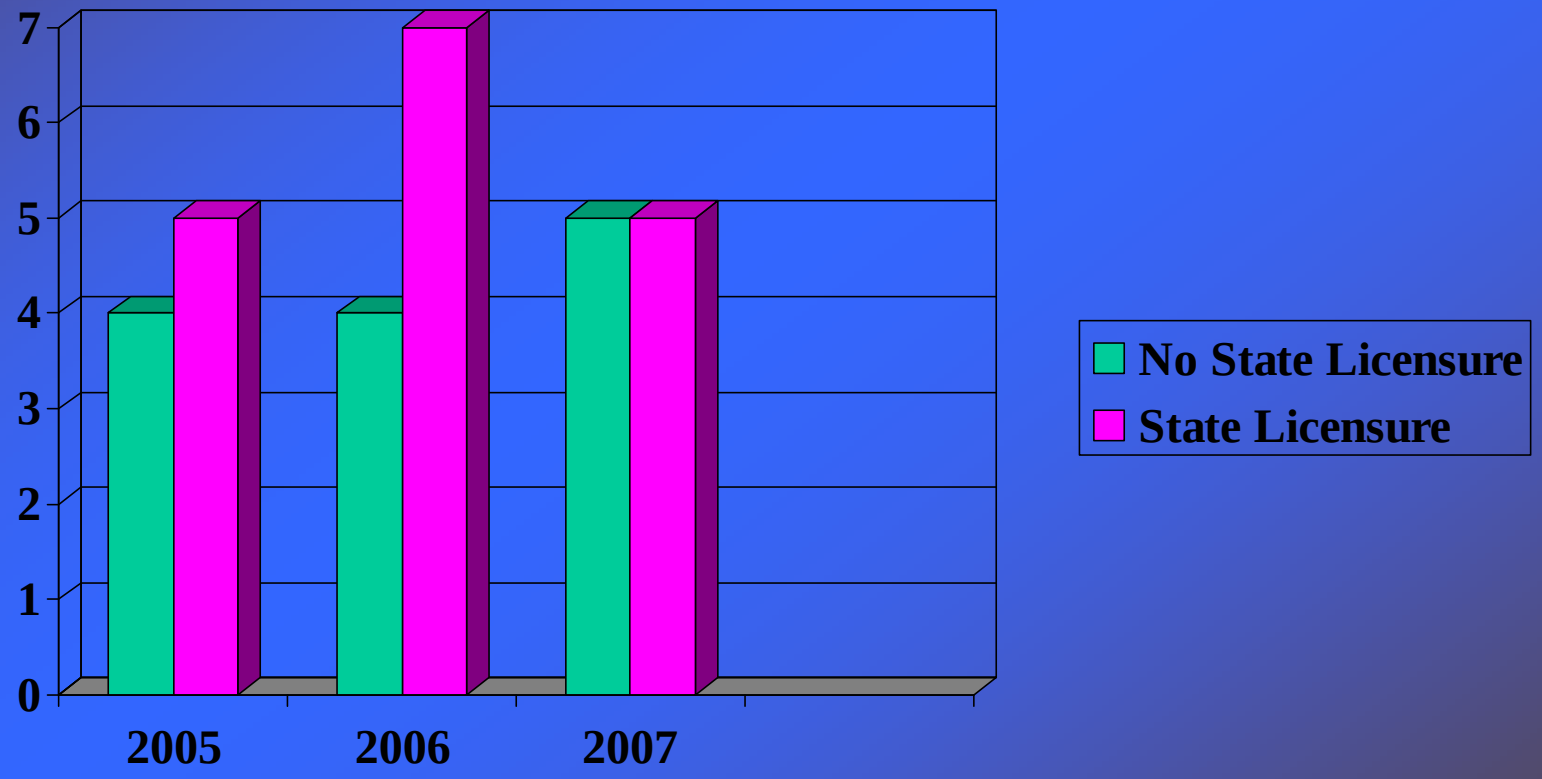
CW Labs Participating in Voluntary Proficiency Testing



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CW Lab Performance with Voluntary Proficiency Testing

CW Survey Response	PT	No PT
Lab has current manufacturer's instructions	98%	88%
Performs required QC	95%	75%
Performs required function checks or calibration	75%	62%
Performs confirmatory testing	25%	15%

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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 to convene w/ Partners/CDC to complete long & short term plans.

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CMS' Plan for Waived Testing

- **Short term**
  - Continue CW project indefinitely
  - Provide edu. materials w/ ea. new ap, on web site, w/ on-site visits, etc.; update clearinghouse
  - Initiate more comprehensive test menu collection
  - Collaborate w/ Partners/CDC to ID add'l. efforts
  - Enlist support of med., mfgr. & patient advocacy orgs.
  - Solicit data from AO/ES w/ CW standards
  - Coordinate w/ FDA on overlapping issues
- **Long term**
  - Change the CLIA law to improve level of oversight

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Electronic Health Records

- Laboratory test result transmission is prototype
- CLIA requires results to State authorized person
  - Or individual who will use them
  - Or referring laboratory
- CLIA requires certain data elements
- CLIA requires accurate, timely, reliable & confidential transmission regardless of mechanism
- New CMS guidance to clarify for EHRs forthcoming!
- **Issues:** State laws, incompatible systems & terminology, lab responsibilities, oversight of EHRs & HIEs

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New Complaint Brochure

- Hot off the press!
- Result of GAO CLIA audit
- Provides simple mechanisms for anyone to file a complaint
- Will be distributed to all labs over next 2 yrs.
- Is on CLIA web site
- Will be available at professional meetings

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CMS 2009 Complaint Data

- 81 complaints received; 27% substantiated
  - Compliance labs—20
  - Accredited labs—52
  - Waived labs---3
  - PPM labs---6
- All complaints investigated; most complaints generate an on site survey.

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CLIA Personnel Policies

Applicable Regulations

Subpart M-Covers mod., PPM & high complexity

- **§493.1351-§493.1495**
- **Laboratory Director (LD)**
- **Clinical Consultant (CC)**
- **Technical Consultant & Supervisor (TC/TS)**
- **General Supervisor (GS)**
- **Testing Personnel (TP)**
- **Cytology General Supervisor (CGS)**
- **Cytology Technologist (CT)**

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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.

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CLIA Personnel Policies

- Phlebotomists, micro plating personnel, clerks, reagent & specimen prep, etc. who do not test are NOT reviewed.
- Agency evaluations are not acceptable, except for foreign credentialing equivalency purposes.
- 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.

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CLIA Personnel Policies

- Consider test complexity when evaluating creds.
- Foreign educated individuals should be evaluated by a nationally recognized agency for equivalency.
- If an individual doesn't meet the edu., training or experience requirements, position isn't filled or position's responsibilities not met, a condition level requirement must be cited.
- Competency is assessed routinely per the regulations for LD & 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 $$.
- Number of false aps recorded thus far: 70!!
- ASCP discovered individuals who submitted false creds. for their certification.
- Surveyors must evaluate creds. consistently; a specific policy facilitates consistency.

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CLIA Personnel Policies

Rationale:

- Mandatory citations also facilitate consistency—a fall out of GAO Report in 2006. Individuals are qualified or not; this isn't considered educational.
- 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.

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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.
- VA discovered falsified degrees.

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CLIA Personnel Policies

Rationale:

- Many shell labs caught by pre-approval review of application creds.
- IJ in lab where GS had no foreign equivalency done.
- TP w/ no HS or 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

Outcomes:

- AOs have condition level citations on CMS valid. surveys & increase disparity rates.
  - 3 yrs. of data reflects personnel as high % of validation citations—20% of surveys.
  - Impacts credibility & re-approval of AOs.
- Patients could be hurt.
- Medicare/Medicaid defrauded of significant sums.

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CLIA Personnel Policies

Outcomes:

- CMS most frequently cited condition level deficiencies reflect personnel qualifications.
  - % of citations decreased since 2007.
- CMS' policy now provides time frame to obtain documentation.

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CLIA Personnel Policies

GOAL:

All oversight agencies have & enforce consistent personnel policies.

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Where to Find Info:

- **CMS CLIA Web site:**
  - www.cms.hhs.gov/clia/
  - NEW FEATURE: “Lab Demographic Look- Up”
  - Brochures, state contacts, application, guidelines, data
- **CMS Central Office, Baltimore**
  - 410-786-3531
- **Judy Yost’s email:**
  - Judith.yost@cms.hhs.gov

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THE END!!

THANK YOU!!

QUESTIONS???

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