

CLIA UPDATE

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Topics for Discussion

- CLIA Data
- Status of Regulations
- IQCP
- Resources

Current Statistics-Enrollment

<u>Total Number of Laboratories</u>	<u>235,828</u>
<u>Total Non-Exempt</u>	<u>228,535</u>
<u>Compliance</u>	19,235
<u>Accredited</u>	15,760
<u>Waived</u>	156,653
<u>Provider Performed Microscopy</u>	36,887
<u>Exempt</u>	<u>7,293</u>
NY	3,583
WA	3,710

CMS data base 1/2013



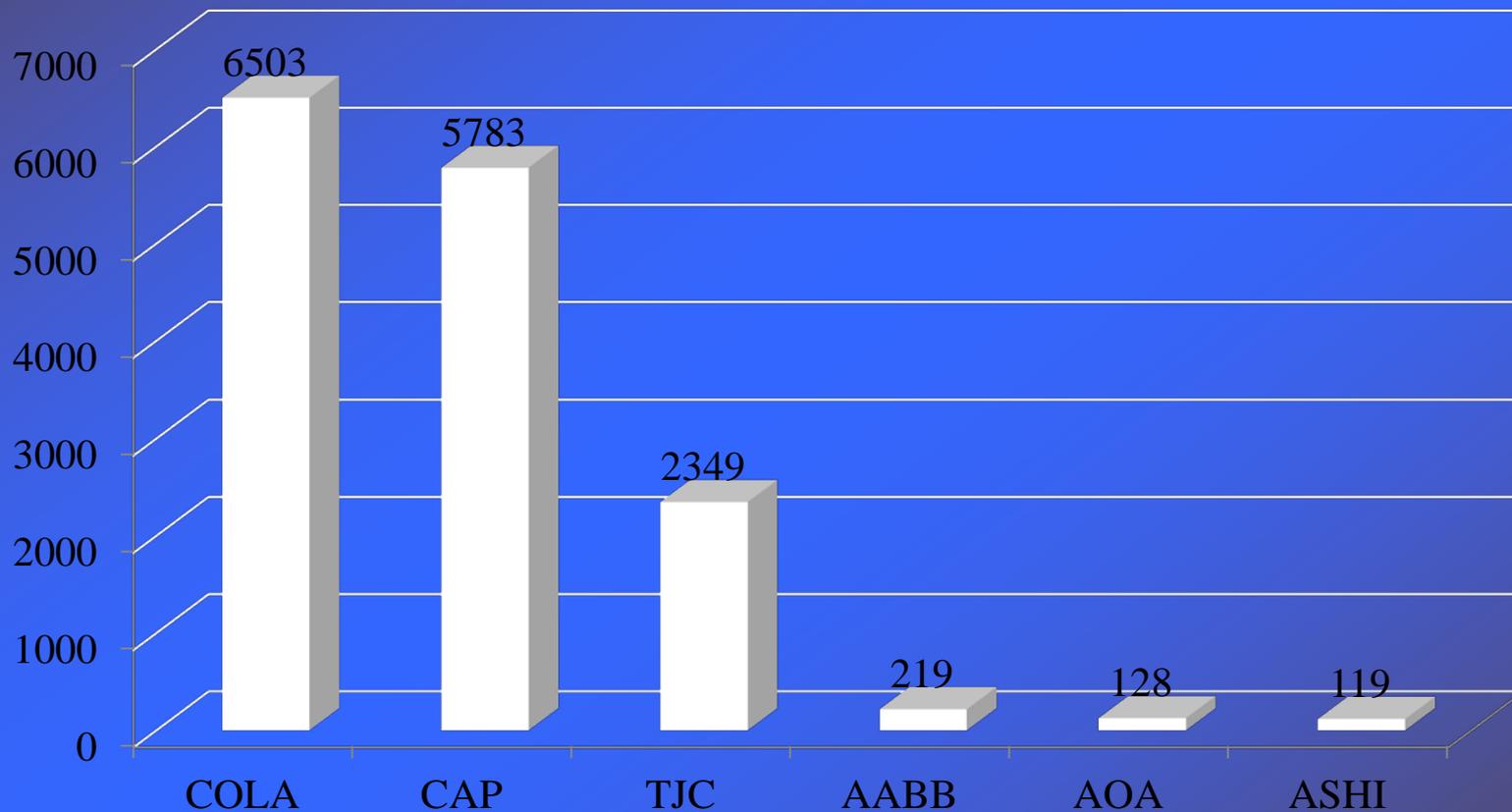
Current Statistics

Physician Office Laboratories by CLIA Certificate Type

(Non-Exempt Only)

Waiver:	58.8%
Provider Performed Microscopy:	25.4%
Compliance:	10.8%
Accreditation:	4.9%

Number of CLIA Certificate of Accreditation Laboratories by Accreditation Organization



CMS 2319-P: Patient Access Rule

- Proposed rule currently undergoing clearance with tentative publication date of late summer 2013
- CLIA Interpretive Guidelines will be revisited to ensure laboratories & stakeholders have clear guidance on best practices/resources to implement Health Information Technology.

Taking Essential Steps for Testing Act of 2012 (TEST Act – HR 6118)

- Amendment to the CLIA statute signed by President on 12/4/12
- Clarifies that PT samples are to be tested in the same manner as patient specimens EXCEPT that no PT samples shall be sent to another laboratory for analysis

Taking Essential Steps for Testing Act of 2012 (TEST Act – HR 6118)

- Allows the Secretary discretion for:
 - Revocation of the CLIA certificate for PT referral; and
 - Imposition of the 2 year owner/operator ban when sanctioned for PT referral

Taking Essential Steps for Testing Act of 2012 (TEST Act – HR 6118)

- Next steps:
 - Rulemaking to detail adverse actions for PT referrals (define when the discretion will be applied and when revocation will be imposed)

PT Referral Update

DO NOT SEND PT SAMPLES TO ANOTHER LABORATORY!!

- CMS Central Office continues to review all cases
- Reflex, confirmation, distributed, referral testing, common personnel across several laboratories seem to be major causes
- Guidance--
 - Read & Follow CMS PT Brochure

Inception of EQC

2003 CLIA Regulations

- In lieu of changing regulations with new technology:
 - Provision in CMS' Interpretive Guidelines (IG), for alternative QC as long as “equivalent quality testing” is provided--- *42 CFR 493.1250 & 1256(d)*.
- Default: 2 levels external QC/day of testing

EQC Follow Up

- Equivalent QC or ‘EQC’ developed in IG as a voluntary alternative QC—2004
- Many laboratories adopted EQC successfully & have no quality issues; but no flexibility
- Concerns expressed by industry, laboratories, experts, etc.

QC for the Future

- ‘QC for the Future’ meeting convened in 2005 by CLSI
- Outcome:
 - Stakeholder concern that manufacturers don’t provide labs sufficient information
 - ‘One-size-fits-all’ QC doesn’t work w/ new technology

Designing The “Right QC”

- CLSI and experts group directed the development of Evaluation Protocol (EP)-23—Laboratory Quality Control Based on Risk Management

Published October, 2011

The “Right QC” is IQCP

- CMS is incorporating key EP-23 concepts into CLIA Interpretive Guidelines (IG) as an acceptable QC policy called IQCP

The “Right QC” is IQCP

- Applies to CMS-certified non-waived labs and will be optional (Default is regulation - 493.1256(d)(3))
- Covers all phases of the testing process, not just QC
- Permits labs to develop an IQCP using their existing quality practices/information (such as test verification data)

The “Right QC” is IQCP

- Includes existing & new analytes/test systems & specialties, except cytology/histopathology
- May or may not reduce QC amt. or frequency
- Considers known risks mitigated by mfg.
- Formalizes laboratories’ risk mgt. decisions

The “Right QC” is IQCP

- Can be customized based on labs’ patient populations, environment, test system, personnel, test uses
- Offers flexibility to achieve QC compliance for each test
- Adaptable to future technology advancements

The “Right QC” is IQCP

- Once effective, IQCP will supersede the current EQC policy
- There will be no changes to the existing CLIA regulations, outcome oriented survey, QC & quality system concepts!
- Labs must also follow mfg.'s instructions
- Lab director has overall responsibility for QCP

Education & Transition Period for IQCP – Laboratories

There'll be an education & transition period for labs before IQCP is fully effective

Info and Guidance will be provided to labs

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

For Questions: **IQCP@cms.hhs.gov**

Education & Transition Period for IQCP - Laboratories

In the interim, CMS certified labs should:

- Continue to follow existing QC protocols
- Learn about EP-23 concepts & IQCP
- Plan & complete their transition accordingly
 - Phase out EQC (if using it)
 - Decide to implement default QC or IQCP

Education & Transition Period for IQCP

- CMS will notify labs of important dates:
 - Beginning of transition & education period
 - End of education & transition period
- At the end, labs must be in compliance w/ their QC choice or deficiencies will be cited

Education & Transition Period for IQCP

- CMS will solicit accrediting orgs (AO) to determine their interest in IQCP
- Accredited labs should continue to meet their accrediting org.'s QC standards until they receive notice from their AO

Education & Transition Period for IQCP

No control procedure regulatory citations will be issued prior to the end of the education & transition period unless serious test quality problems are found

Where to Obtain Information

CMS/CLIA Web site:

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

CMS CLIA Central Office: 410-786-3531

Judy Yost's Email: Judith.yost@cms.hhs.gov

IQCP Link: http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.html