

CLIAC Update – Fall 2016

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Personnel Changes

David R. Wright

Director of Survey and Certification Group

Regina Van Brakle

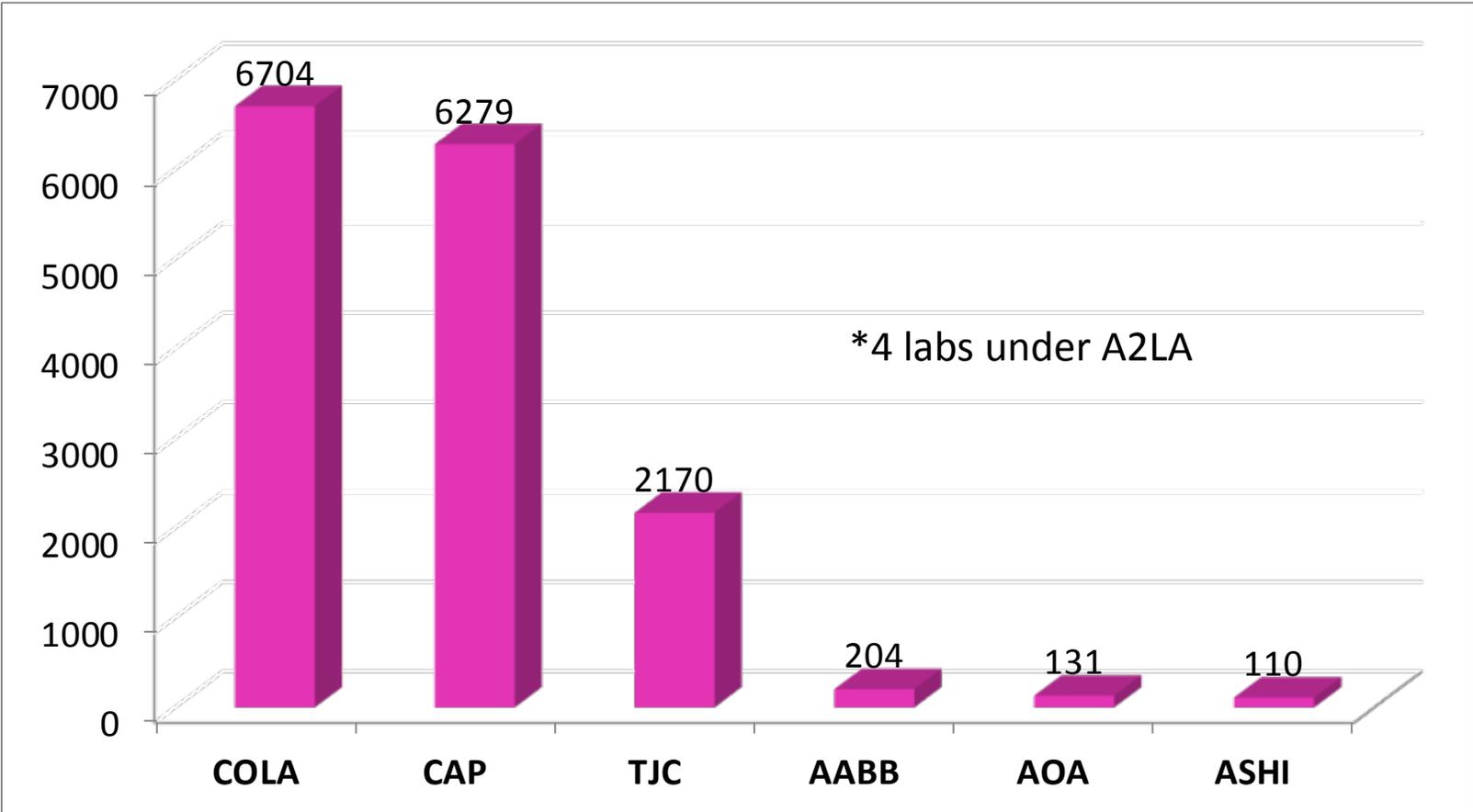
Deputy Director of CLIA

Current Statistics--Enrollment

<u>Total Number of Laboratories</u>	254,975
<u>Total Non-Exempt</u>	246,650
<u>Compliance</u>	18,385
<u>Accredited</u>	16,441
<u>Waived</u>	177,016
<u>Provider Performed Microscopy</u>	34,808
<u>Exempt</u>	8,325
NY	4,256
WA	4,069

CMS data base 6/2016

CLIA Certificate of Accreditation Laboratories



CMS data base 6/2016



CLIA Modernization

- Staff from The House Energy and **Commerce** Committee have met several times with CLIA and FDA staff regarding each Agency's respective oversight authority and responsibilities regarding LDTs.
- CMS CLIA has provided Technical Assistance on the Draft Legislation before the Committee
- As of October 1st, no decision from the Committee as to Status of the draft Legislation

Precision Medicine Initiative

- CLIA issue: researchers wish to provide participants with genomic test results that were obtained in non-CLIA certified research laboratories.
- CLIA certification is intended to ensure accurate test results. Without CLIA certification, patients and health care providers cannot be assured of the test result's analytic validity, potentially leading to misdiagnosis and treatment.
- Participation in multiple calls with FDA, CDC, NIH, OCR regarding potential issues with return of results to participants
- Preparation of multiple briefing documents, in addition to a cost model of what it would take for a research laboratory to obtain a CLIA certificate

SOM Chapter 6 Revisions

- Updating the State Operations Manual (SOM)- initiated January 2016
- SOM has not been revised since 2009
- To include all S&C memoranda issued by CLIA/CMS since last revision
- Publish date – early 2017

CLIA GPRA Goal

- The Certificate of Waiver goal was discontinued at the completion of the FY 2016 CW project survey cycle (September 2016).
- The new goal will concentrate on surveying Provider Performed Microscopy (PPM) labs and will begin in FY18 – pending OMB approval.
- PPM procedures are considered to be a subset of moderate complexity tests.

Surveyor Consistency

Goals:

- Ensure consistency of training for all Surveyors
- Ensure consistency of surveying between surveyors

Processes used to achieve goals:

- Virtual Basic Training
- Structured SA Surveyor Training
- Federal Monitoring Surveys

CLIA Virtual Basic Training Update

- Final updates and voice overs in progress with scheduled delivery early 2017
- Multiple modules to be available 24/7 via Web
- NOTE: All CMS surveyors will be required to complete the training modules

Structured SA Surveyor training

- Create a structured training process for all states to use for new CLIA surveyors
- Ensure each surveyor gets the same basic information on the survey processes
- Each SA can add specific state requirements to this training

Principles of Documentation

- Updating the Principles of Documentation to provide:
 - Clarification of language
 - Addition of more current examples
 - Appendices that provide additional examples and surveyor tools

Goal – Web based, interactive training available 24/7 for surveyors

Primary Source Verification (PSV)

- Any organization that confirms an individual's credentials by verifying that a degree, certificate, or diploma was received ; that licenses were granted; AND, by confirming reported work history, such as company names and locations, dates, and positions held is a considered PSV organization.
- **CMS is not issuing standards to be applied to PSV organizations.**

Nursing Degree

- Bachelor's and Associate's degrees in nursing meet the requirement for earning a degree in a biological science for, respectively, high complexity testing personnel and moderate complexity testing personnel.
- In addition to academic qualifications, CLIA requires training and competency assessment for all laboratory personnel.
- This is not a new policy (clarification of previous existing policy)
- Laboratories can adopt higher standards than the federal regulation.

Drug Testing Laboratories

Multi-faceted problems:

- Proliferation of pain treatment facilities
- CLIA laboratories for sale on internet
- No labs at physical location
- Lab Director qualifications
- Multiple CLIA numbers
- Possible fraudulent LD name/billing practices

Drug Testing Laboratories-Solutions?

- Investigate changes to CLIA application process?
- Regulatory changes?
- Require procedures/validation documentation up front?
- Establish Task Force consisting of CO/RO CLIA, CMS Billing and Payment groups, OGC, OIG?

CLIA and Biosafety

- CLIA does not specifically address but there are existing regulations that could be used to address Biosafety and Risk Management Assessment

REGULATIONS	
493.1101 (a) (1)	493.1407 (e) (2)
493.1101 (a) (2)	493.1407 (e) (10)
493.1101 (b)	493.07 (e) (11)
493.1101 (c)	493.1407 (e) (12)
493.1101 (d)	493.1445 (e) (2)
493.1235	493.1445 (e) (11)
493.1241 (C)(8)	493.1445 (e) (12)
493.1254 (a)(1)(2)	493.1445 (e) (13)

Outreach Activities

- Desire to inform future Medical Technology students about the regulatory environment they will encounter once they enter the laboratory workforce.
- Baltimore area MT/MLT schools contacted regarding interest in this type of information – positive response.
- Tentative plans to start outreach – early 2017