

Clinical Laboratory Improvement Amendments (CLIA)

CLIAAC Update November 2019

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Current Statistics--Enrollment

<u>Total Number of Laboratories</u>	265,673
<u>Total Non-Exempt</u>	256,114
<u>Compliance</u>	17,480
<u>Accredited</u>	15,732
<u>Waived</u>	192,332
<u>Provider Performed Microscopy</u>	30,570
<u>Exempt</u>	9,558
NY	5,464
WA	4,094

CMS data base 10/2019

Certificate Types-1993 thru 2019

Lab Type	Year	Year	Year	Year	Year	Year	Year
	1993	1995	2000	2005	2010	2015	2019
Compliance	44,762	37,578	25,068	20,480	19,404	18,385	17,480
Waiver	67,294	65,031	85,944	113,445	141,994	177,016	192,332
PPM	16,443	23,089	35,760	39,205	37,795	34,808	30,570
Accredited	23,751	19,426	16,992	15,607	15,864	16,441	15,732

Impetus for CLIA 1988

Five issues identified by Congress:

1. Lack of proficiency testing
2. Cytology testing occurred in homes without oversight
3. No limit on the number of cytology slides an individual could examine
4. Lack of slide reviews by laboratory management
5. Lack of trained individuals to perform surveys in cytology laboratories

CLIA Authority/Regulations

- CLIA law Section 353(e) of Public Health Service Act (PHSA) -Enacted on 10/31/88
- CLIA regulations published 2/28/92, effective 9/1/92 as 42 CFR Part 493

CLIA update 2003

- Update to the CLIA regulations (published as final rule, effective 4/24/2003) included:
 - Quality control provisions
 - Quality systems for non-waived testing by consolidating and reorganizing the requirements
 - Personnel qualifications
 - Consensus requirement for grading proficiency testing challenges

CLIA Regulations

- CLIA established uniform quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed
- CLIA applies to all entities which conduct testing on human specimens for health purposes

CLIA Program

The CLIA program is entirely user-fee funded by the laboratories it oversees; therefore, CLIA receives no funds from Congress or CMS.

CLIA Approves.....

- Laboratory Accreditation Organizations (AOs) such as the Joint Commission and the College of American Pathologists (CAP) as deeming organizations for CLIA as well as Exempt states (ES) NY and Washington.
- AOs must meet the minimum CLIA regulations but they can also be more stringent than CLIA

AO/ES Re-approval History

- Review process updated in 2011 to be a more simple, standard, efficient and effective process
- Revised process piloted in two AOs
- Implemented updated process in March 2012 for all AO/ES

AO/ES Re-approval

- Scheduling process is the same for ALL
- Adherence to schedule
- AO/ES submits final material only—no changes until project complete
- Courtesy call to the AO/ES in advance of solicitation letter
 - To include a high level schedule of deliverables for both CMS and the AO/ES
- RO individual included in review process

AO/ES Re-approval

- Reapproval process takes approximately 1 year
 - AO submits package including crosswalk of AO requirements to CLIA regulations
 - CMS Review team consists of CO and RO participants
 - Desk review of submitted material
 - On-site visit to AO headquarters to audit records (surveys, complaints, PT monitoring, etc.)
 - Reapproval of up to 6 years published in FR

CLIA Approves.....

- 10 Proficiency Testing programs
- Programs approved on an annual basis

CLIA Approval of PT Programs

- PT programs apply for CMS-approval initially, and annually thereafter, to ensure that they are in compliance with Subpart I
- After the initial approval, PT programs are required to reapply for CMS approval annually no later than July 1 for the next year.
- PT programs are extensively evaluated to ensure they meet all program requirements as outlined in Subpart I of the CLIA regulations

CLIA Approval of PT Programs

- PT programs are required to have at least 3 events per year consisting of a minimum of 5 challenges per event for all analytes listed in Subpart I and all specialties and subspecialties, except for mycobacteriology, which only requires 2 events per year.
- The list of the CMS-approved PT programs with the specialty/subspecialty, and analytes for which they are approved in each year is on the CMS CLIA website [<https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/ptlist.pdf>].

Test Complexity

CLIA requirements are based on test complexity:

- Waived
- Non Waived
 - Moderate Including Provider Performed Microscopy testing (PPM)
 - High
- The more complex the test, the more stringent the requirements

Test Categorization

- FDA performs test categorization for CLIA
- CLIA Regulations regarding the process for test categorization are found at §493.17

Types of CLIA Certificates

- Certificate of Waiver (CoW)
- Certificate of Provider-Performed Microscopy (PPM)
- Certificate of Compliance (CoC)
- Certificate of Accreditation (CoA)
- Certificate of Registration (CoR)

Research exception (§493.3(a)(2))

- Research laboratories that test human specimens but do not report patient specific results for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of individual patients

Certificate of Waiver (CoW)

- Can only perform waived tests
- Exempt from routine surveys
- Subject to announced or unannounced surveys under certain circumstances (i.e., complaint)
- Required to follow manufacturer instructions for performing a test
- No personnel requirements

Certificate of PPM

- Can perform PPM + waived tests
- Exempt from routine surveys
- Subject to announced or unannounced surveys under certain circumstances (i.e., complaint)
- Midlevel practitioner
 - Nurse midwife
 - Nurse practitioner
 - Physician Assistant

Certificate of Compliance (CoC)

- Can perform waived, PPM, moderate and high complexity testing
- Subject to biennial surveys
- Complaint surveys
- Facility Administration, Quality Systems, Personnel, Proficiency Testing requirements

Certificate of Accreditation (CoA)

- Accreditation Organization performs survey to determine compliance
- Subject to validation and complaint surveys by CMS
- Can perform waived, PPM, moderate and high complexity testing
- If only performing waived and PPM testing, a laboratory cannot have a CoA

Inspection Requirements

- Applies to all certificate types
- Laboratory must allow access to assess compliance with requirements
- Laboratory must provide upon request, all information required to determine compliance
- CMS or its agent may re-inspect and perform complaint surveys
- Failure to permit an survey results adverse action

Outcome-Oriented Survey Process

- Principal focus is the effect (outcome) of the laboratory's practices on patient test results and/or patient care
- Surveyor reviews and assesses the overall functioning of the laboratory and evaluates the laboratory's ability to perform quality testing (i.e., accurate, reliable and timely test results)

Outcome-Oriented Survey Process

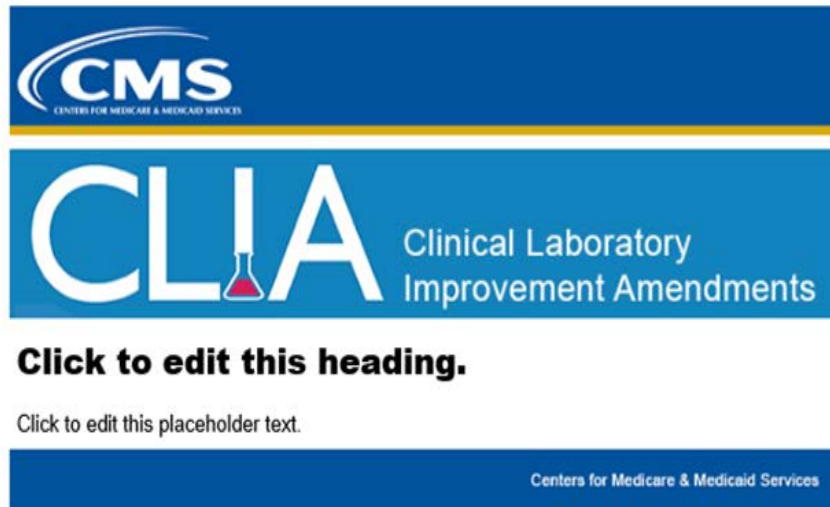
- Emphasis on the laboratory's quality system as well as the structures and processes throughout the entire testing process that contribute to quality test results
- Surveyor selects a cross-section of information from all aspects of the laboratory's operation for review
- Survey has the ability to expand a survey if quality issues are found

CLIA Communications Listserv

GOAL: to disseminate information to laboratories and laboratory professionals -the public can subscribe in order to get updates directly from CLIA

From

Centers for Medicare & Medicaid Services <cmslists@subscription>



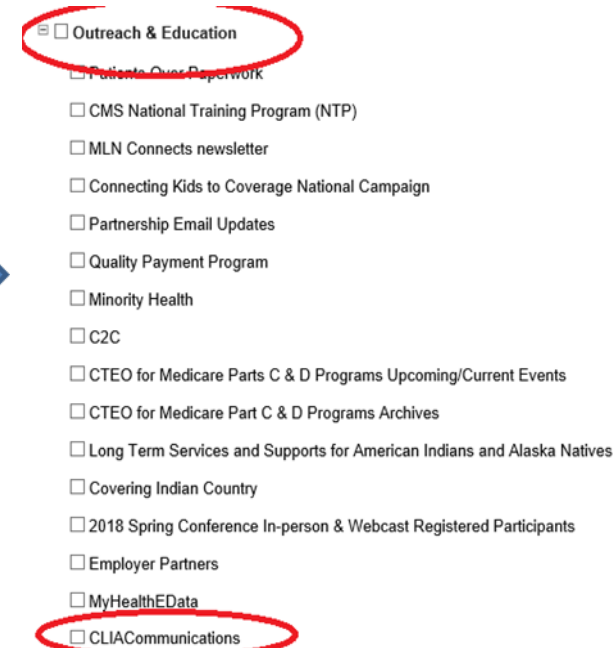
https://public.govdelivery.com/accounts/USCMS/subscriber/new?topic_id=USCMS_12461

CLIA Communications Listserv

- The web address below will take you to CMS.gov.
- When you scroll to the bottom of the page, you will see the “Receive Email Updates” section.
- Enter your email address and follow the instructions.



- Scroll through the choices until you find the “Outreach & Education” section.
- Click the “CLIA Communications” option at the very bottom of the page.
- Hit “SUBMIT”
- You are now subscribed to the listserv!



https://public.govdelivery.com/accounts/USCMS/subscriber/new?topic_id=USCMS_12461


This is an example of a CLIA Listserv Bulletin



As of October
2019
there are
7862 subscribers
to the CLIA
Communications
Listserv!

From: Centers for Medicare & Medicaid Services <cmslists@subscriptions.cms.hhs.gov>
Subject: Welcome to the CLIA Communications Listserv

Hello From the CLIA Program!



Hello to all CLIA Communications Subscribers!

Thank you so much for subscribing to the Clinical Laboratory Improvement Amendments (CLIA) Communications listserv.

We have heard you! You would like more real time information from our program! We are excited to be able to bring information directly to you!

The goal of this email listserv is to disseminate important updates and information to laboratories and laboratory professionals.

Subscribers will receive alerts and communications from CLIA Central Office in the event of a public health emergency. CLIA CO is also considering messaging subscribers when new regulations and policy memos are released.

CLIA Outreach Goals

- Provide Medical Laboratory Science students with a basic knowledge of CMS/CLIA
- Demonstrate the direct link between compliance with CLIA regulations and the production of high quality clinical laboratory testing.
- Promote Clinical Laboratory Science(CLS) as a vital and dynamic career for high school and post-secondary students.

COPA 2016 – 2019

- The Division of Clinical Laboratory Improvement and Quality (DCLIQ) created the CLIA Outreach Program – Academic (COPA) in the summer of 2016.
- Targeted - Allied Health students with 2 to 4 year Laboratory Science Programs (*Associate or Bachelor Degrees*) CLS and Medical Laboratory Technicians.
- In 3 1/2 years COPA has built a school client list from 8 to 20 and have reached over 250 students.
- Provide website information/50 minute presentation – CLIA-101

COPA Continues Growth

- Collaboration with Healthcare Students of America (HOSA), regional state chapters to participate in their competitions.
- Continue with post-secondary growth for schools with CLS/MLT programs within a 2 ½ hour drive of Baltimore.
- Given the growth of Point of Care Testing (POCT) expand the proposed school list to offer the COPA presentation to Nursing/Medical schools -2019/2020?
- Explore options with professional organization to offer regulatory education by video produced at CMS.

Contact Information

- CLIA Central Office: 410-786-3531
- LabExcellence@cms.hhs.gov