CMS CLIAC Presentation

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Disclaimer

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This publication is a general summary that explains certain aspects of the CLIA Program, but is not a legal document. The official CLIA Program provisions are contained in the relevant laws, regulations, and rulings. Links to the source documents have been provided within the document for your reference.

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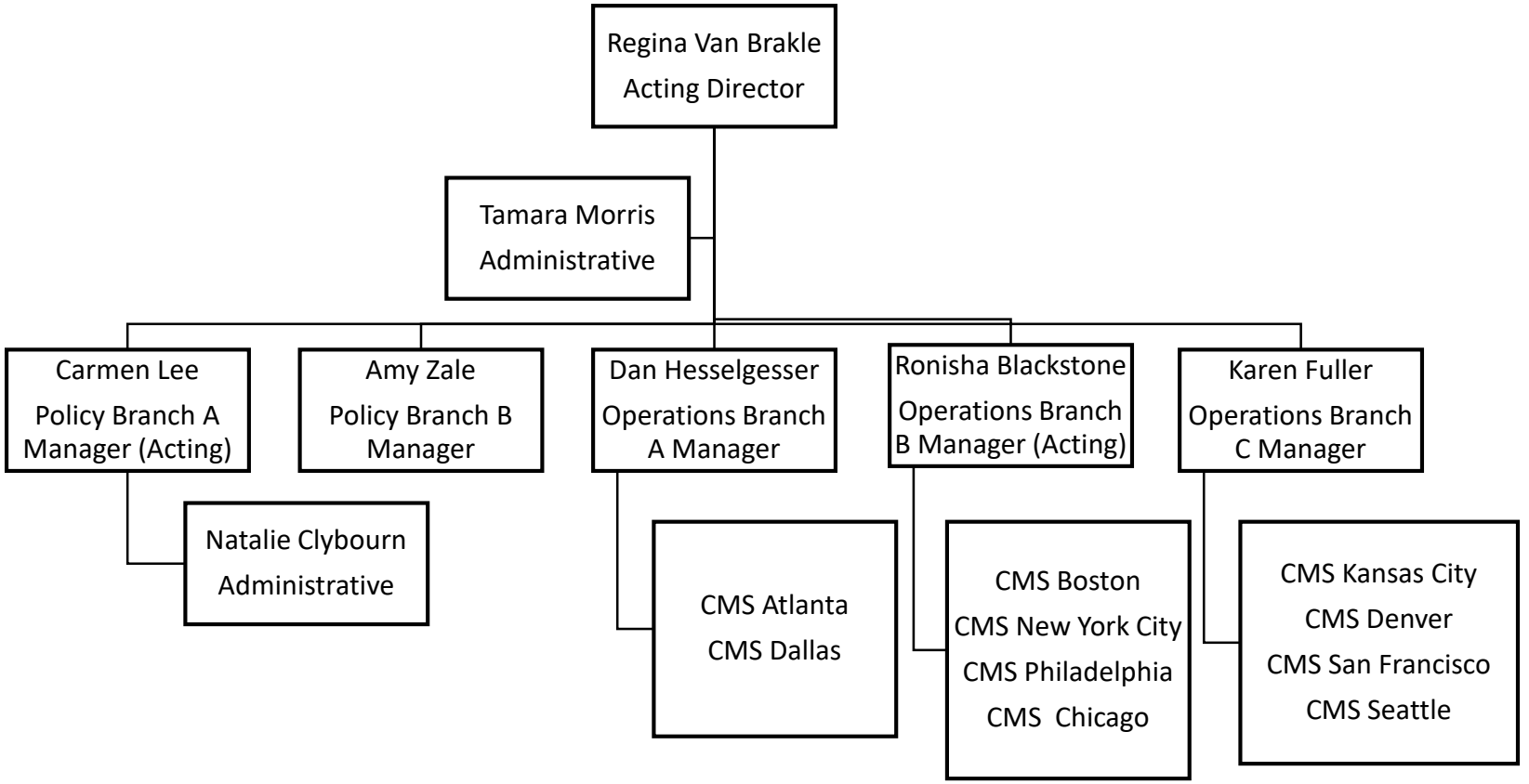
CMSOne Re-alignment



CLIA Pay Banner and CLIA Quick Start Guide

- Availability of an online payment system for the Clinical Laboratory Improvement Amendments (CLIA) certification fee.
- New quick start guide available to laboratories applying for CLIA certification to help with the application process for CLIA certification and includes information on the expedited review process that allows labs to start testing quickly.

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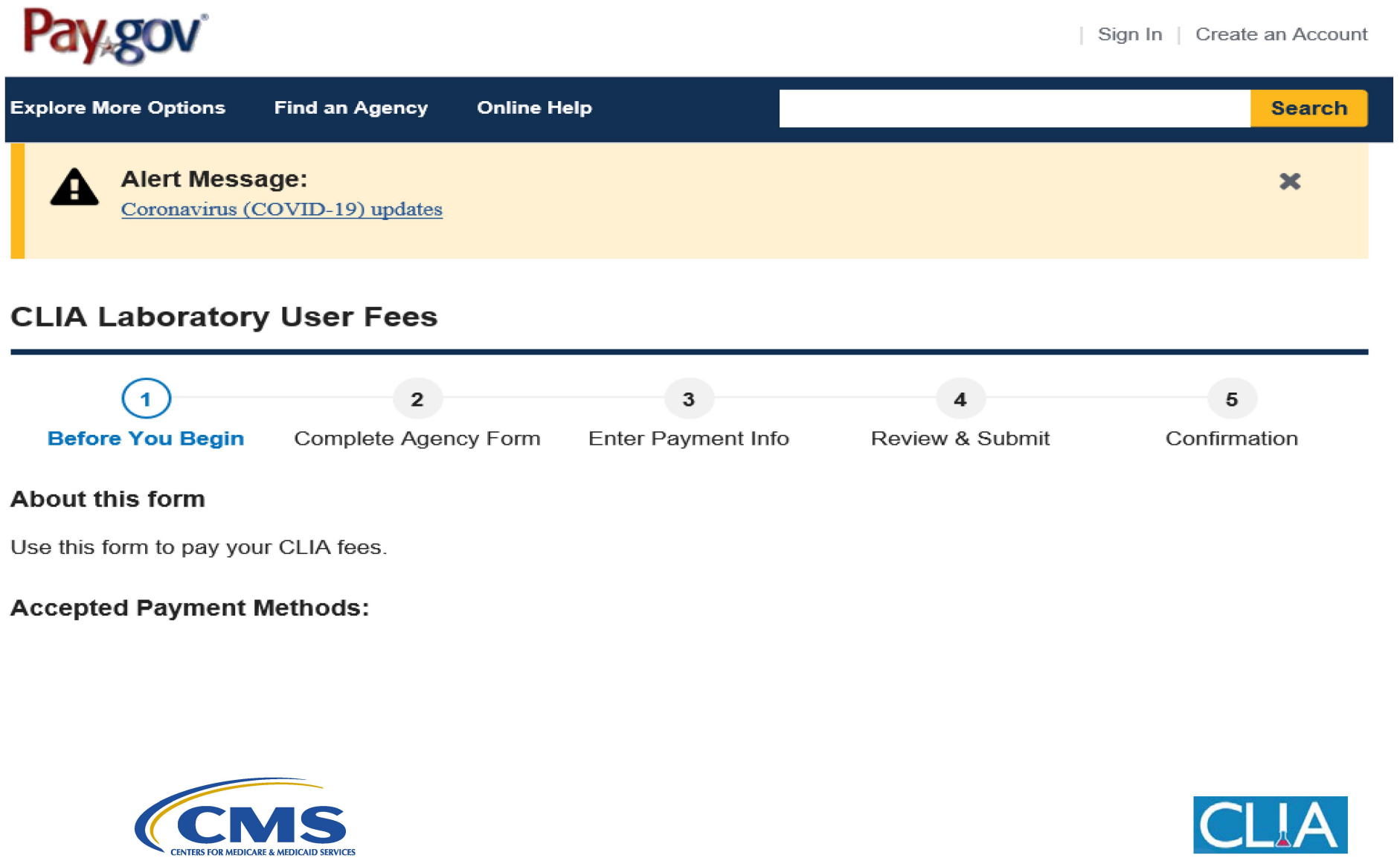
CLIA Pay Banner



CLIA Quick Start Guide

LABORATORY QUICK START GUIDE TO CMS CLIA CERTIFICATION

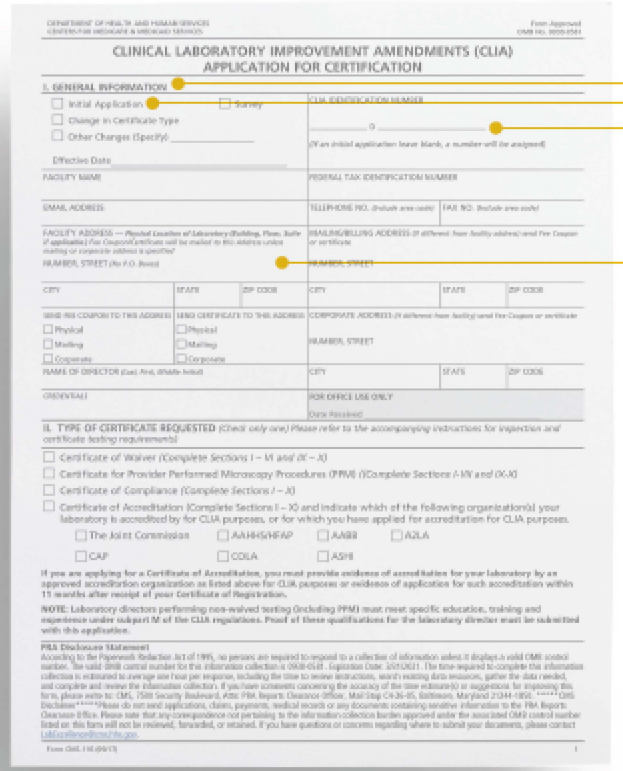
SEPTEMBER 2020

Laboratory Quick Start Guide to CMS CLIA Certification

The Centers for Medicare & Medicaid Services (CMS) Clinical Laboratory Improvement Amendments (CLIA) regulates the quality and safety of U.S. clinical laboratories to ensure the accuracy, reliability, and timeliness of patient test results regardless of where the test was performed. CLIA has regulatory requirements for quality that all laboratories must meet. This guide helps laboratories seeking to apply for CLIA certification from CMS. More information can be found on the CMS CLIA website.

STEP 1: Download and Complete Form CMS-116

- Include information based on the date of form completion.
- All applicable sections must be completed. Incomplete applications cannot be processed.
- Print legibly or type.
- To find out if the testing your laboratory is performing is categorized as waived, moderate, or high complexity-refer to the FDA website. If you are unable to locate the test complexity of your laboratory testing, contact your State Agency.
- For a complete list of instructions, refer to page 6 of Form CMS-116.



CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA)
APPLICATION FOR CERTIFICATION

I. GENERAL INFORMATION

II. TYPE OF CERTIFICATE REQUESTED

Complete General Information in section I.

- First-time applicants check "Initial Application."
- For an initial applicant, the **CLIA Identification Number** is left **blank**. When the application is processed, the number is **assigned**.
- **Facility Address** must reflect the physical location where the laboratory testing is performed. The address may include a floor, suite and/or room location, but cannot be a Post Office box or Mail Stop.

International Lab Facilities

For CLIA purposes, an international laboratory is a facility outside the U.S. or its territories that performs clinical laboratory tests referred by and returned to a facility in the U.S. or its territories.

Disclaimer: This guide is a restatement of the law intended to assist people in understanding the basics about the CLIA program, and that the reader should consult the relevant statutes and regulations for the full scope of the CLIA requirements.

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Current Statistics

Total Number of CLIA Laboratories	**282,518**
Total Exempt States (NY & WA)	10,613
Total Non-Exempt	271,905
• **CoW**	207,858
• **PPM**	30,097
• **CoC**	18,015
• **CoA**	15,935

Source: CMS database - October 2020

Current Statistics

Total Number of New CLIA Laboratories since March 2020	17,098
• CoW	15,308
• PPM	584
• CoC	774
• CoA	432

Source: CMS database - October 2020

Current Statistics – Skilled Nursing Homes & Pharmacy Initiative

Top Facility Types for New CLIA Laboratories Since March 2020	Number
Physician Office Lab (POL)	5,188
Pharmacy	2,866
Other	2,232
Assisted Living Facility	1752
Other Practitioner	681
Independent	632
Home Health Agency (HHA)	592
Nursing Home (SNF/NF)	395

CMS database - October 2020

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Section 1135 Waiver Requests

- The CLIA program is unable to approve section 1135 waiver requests with respect to waivers of CLIA program requirements. The section 1135 waiver authority is only applicable to specified programs (or penalties) authorized by the Social Security Act (SSA). The CLIA program does not fall into this category of programs.

CLIA Flexibilities During the Public Health Emergency

During the PHE, CMS released the QSO-20-21 CLIA memo on March 26, 2020, providing guidance to surveyors and laboratories regarding:

- CMS' Exercise of enforcement discretion to ensure pathologists may review pathology slides remotely if currently defined conditions are met.
- Ensuring that laboratories located in the United States wishing to perform COVID-19 testing that apply for CLIA certification are able to begin testing as quickly as possible during the public health emergency.
- Highlighting that laboratories within a hospital/University Hospital Campus may hold a single certificate for the laboratory sites within the same physical location or street address.
- Offering enforcement discretion as to Proficiency Testing (PT) During the duration of the Public Health Emergency.
- Addressing alternate Specimen Collection.

Enforcement Discretion During PHE

CMS will temporarily exercise enforcement discretion for the duration of the PHE under CLIA:

- For the use of SARS-CoV-2 POC antigen tests on asymptomatic individuals. Specifically, CMS will not cite facilities with a CLIA Certificate of Waiver when SARS-CoV-2 POC antigen tests are performed on asymptomatic individuals, as described in the FDA FAQ
- For SARS-CoV-2 surveillance testing where patient-specific results are reported (e.g., SARS-CoV-2 surveillance testing that does not utilize a pooling strategy). Specifically, neither CMS nor the State survey agencies on its behalf will cite non-CLIA certified facilities, such as university laboratories, that are performing such testing, provided that the facility does not report actual test results, but only refers an individual with a presumptive positive or inconclusive test result to a laboratory for further testing.

Survey Re-prioritization

During the PHE, CLIA surveys/inspections were placed on hold and then later re-prioritized to focus on the following:

- Complaints that represent situations in which immediate corrective action is necessary because the laboratory's noncompliance with one or more condition-level requirements has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death.
- Any revisit to resolve current enforcement actions.
- Recertification actions for certificates that have been extended to December 31, 2020, and any other soon to expire certificates.
- Initial certifications and other complaints.

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Remote Surveys

- Workload Backlog
- Optional for State Agencies, not mandatory
- Only allowed for laboratories with good compliance history

Cease and Desist Letters During PHE

- Laboratories Testing Without a CLIA Certificate
- Laboratories Testing Outside of the CLIA Certificate

CLIA Tracker Report

Complaint Allegation	CMS Atlanta,	CMS Boston	CMS Chicago	CMS Dallas	CMS Denver	CMS Kansas City	CMS New York	CMS Philadelphia	CMS San Francisco	CMS Seattle	
Testing without CLIA certificate	3.16%	0.53%	5.79%	19.47%	0.53%	0.00%	0.00%	1.05%	3.68%	1.05%	35.26%
Wrong COVID test for certificate	2.63%	0.00%	4.74%	42.63%	0.00%	2.63%	1.58%	7.89%	2.11%	0.53%	64.74%
Total	11	1	20	118	1	5	3	17	11	3	190

Report Execution Date: 09/30/2020 Page Number: 1 of 1

CLIA Communications ListServ and Public Outreach

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

- 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.

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

CLIA Listserv Bulletin Example

Pay Your CLIA Certification Fees Online!

CMS now offers laboratories an online option to pay CLIA certification fees through a secure platform hosted by the Treasury Department.

Online payments are processed overnight, substantially faster than hard-copy checks, which can take up to 10 business days to process.

You can access the online system by clicking on the linked banner below or by entering the following hyperlink in your browser: https://pay.gov/public/form/start/55598674. You can also access the payment platform through the CLIA Program website.

CARES Act

- Coronavirus Aid, Relief, and Economic Security (CARES) Act, requires “every laboratory that performs or analyzes a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19” to report the results from each such test to the Secretary of the Department of Health and Human Services (HHS)

- § 18115 applies to laboratories

CARES Act link: https://www.congress.gov/116/bills/hr748/BILLS-116hr748enr.pdf

New/Modified CLIA Regulations

- These Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations in IFC-3401-CMS address the requirement that all CLIA-certified laboratories must report all SARS-CoV-2 test results
- New CoW reporting requirement added at § 493.41
- Added a requirement at § 493.555(c) requiring Accreditation Organizations(AOs)/Exempt States(ESs) to report to CMS within 10 days condition-level noncompliance with reporting requirements under §§ 493.41 or 493.1100(a)

New/Modified CLIA Regulations (cont'd)

- Reporting requirement for non-waived laboratories added at § 493.1100(a)
- Amended § 493.1804(c) to allow imposition of alternative sanctions on CoW laboratories that fail to report SARS-CoV-2 test results
- Added § 493.1834(d)(2)(iii) to outline Civil Money Penalty (CMP) structure for failure to report SARS-CoV-2 test results

Who Has To Report

- All CLIA-certified laboratories that perform testing for SARS-CoV-2.

- This includes health care facilities using Point of Care COVID-19 testing devices under a CLIA Certificate of Waiver, including nursing homes, pharmacies, or other settings, will be required to report test results under this regulation.

What do I Have to Report

- All SARS-CoV-2 tests results for all types of testing (e.g. molecular, antigen, antibody) regardless of the type of laboratory.

- Each test result for every SARS-CoV-2 test the laboratory performs, regardless of the number of times that an individual is tested.

CLIA Reporting Requirements

- Each laboratory must report SARS-CoV-2 test results in the manner and frequency prescribed by the HHS Secretary.
- CLIA is not prescriptive about how a laboratory documents reporting of SARS-CoV-2 results.
- The laboratory must maintain documentation of their reporting process.

Assessing Compliance

- Surveyors will assess compliance with CLIA test reporting requirements during surveys.

- Surveys include CoW and PPM laboratories.

What Happens if I do not Report?

- Failure to report SARS-CoV-2 test results may result in:
  - Condition-level noncompliance
  - Imposition of a civil money penalty (CMP)
- CMPs
  - $1000 for 1st day of noncompliance
  - $500 for each subsequent day of noncompliance

Not Testing for SARS-CoV-2?

If your laboratory is not performing any testing for SARS-CoV-2, there is nothing that you need to do differently at this time; however…

Please note: If your laboratory decides to start testing you would need to follow the reporting requirements.

Hyperlink Table of Resources

- CMS-3401-IFC: Interim Final Rule
- QSO Memo, IFC, SARS-CoV-2 Test Reporting: QSO-20-37-CLIA, NH
- HHS COVID-19 Reporting Guidance: HHS Reporting Guidance
- QSO Memo, Clinical Laboratory Improvement Amendments (CLIA) Laboratory Guidance During COVID-19 Public Health Emergency + FAQs: CMS QSO-20-21-CLIA
- CMS SARS-CoV-2 Laboratory Testing Comparison + COVID-19 Testing Infographic: ADMIN 20-06-CLIA

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Contact Information

Contact CMS at

LabExcellence@cms.hhs.gov

If inquiry is specific to the IFC,

add “**CMS-3401-IFC”** in the subject header

Thank You!!