



# CMS CLIAC Presentation



*Regina Van Brakle*

*Acting Director*

*Division of Clinical Laboratory  
Improvement and Quality*

*October 28, 2020*

# Disclaimer

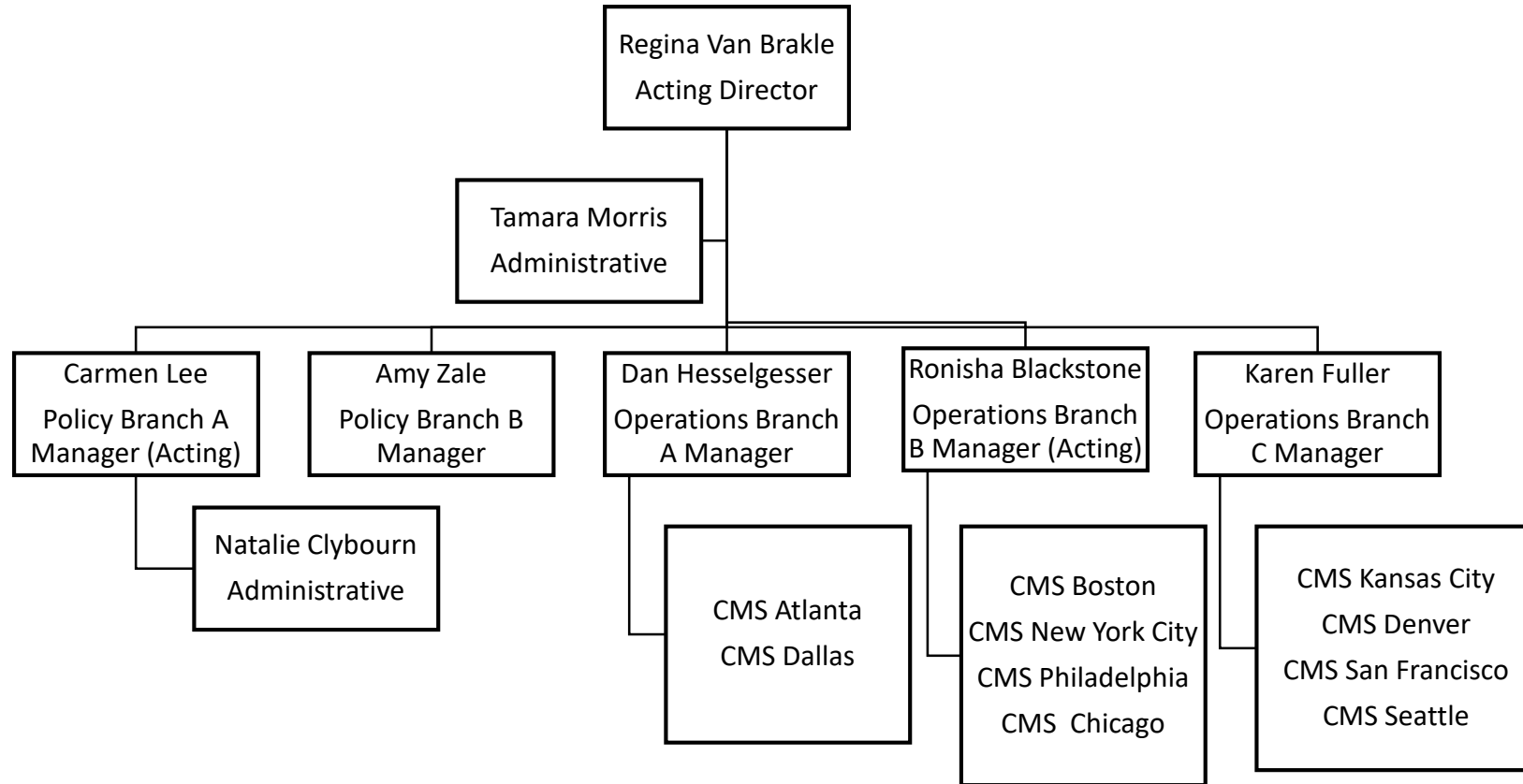
This presentation was prepared for informational purposes and is not intended to grant rights or impose obligations. Every reasonable effort has been made to assure the accuracy of the information within these pages.

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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# CMSSOne Re-alignment



# CLIA Pay Banner and CLIA Quick Start Guide

Clinical Laboratory Improvement Amendments (CLIA)



- 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.

# CLIA Pay Banner



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## CLIA Laboratory User Fees



### About this form

Use this form to pay your CLIA fees.

### Accepted Payment Methods:



# 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](#).

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICAID SERVICES

Form Approved  
OMB No. 0938-0161

### CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) APPLICATION FOR CERTIFICATION

**I. GENERAL INFORMATION**

Initial Application  Renewal  Change in Certificate Type  Other Changes (Specify): \_\_\_\_\_

Effective Date: \_\_\_\_\_

CLIA IDENTIFICATION NUMBER: \_\_\_\_\_

Facility Name: \_\_\_\_\_

Federal Tax Identification Number: \_\_\_\_\_

Facility Address: \_\_\_\_\_

Telephone No. (include area code): \_\_\_\_\_ FAX No. (include area code): \_\_\_\_\_

MAILING/BILLING ADDRESS (if different from facility address) and the Design or Certificate: \_\_\_\_\_

NAME OF DIRECTOR (and title, if applicable): \_\_\_\_\_

CITY: \_\_\_\_\_ STATE: \_\_\_\_\_ ZIP CODE: \_\_\_\_\_

CITY: \_\_\_\_\_ STATE: \_\_\_\_\_ ZIP CODE: \_\_\_\_\_

NAME OF COMPANY TO THIS ADDRESS: \_\_\_\_\_

PHYSICAL:  MAILING:  CORPORATE:

NAME OF DIRECTOR (and title, if applicable): \_\_\_\_\_

CITY: \_\_\_\_\_ STATE: \_\_\_\_\_ ZIP CODE: \_\_\_\_\_

**II. TYPE OF CERTIFICATE REQUESTED** (Check only one! Please refer to the accompanying instructions for inspection and certificate testing requirements.)

Certificate of Waiver (Complete Sections I – M and OI – O)

Certificate for Provider Performed Microscopy Procedures (PPMP) (Complete Sections A-M and OI-O)

Certificate of Compliance (Complete Sections I – J)

Certificate of Accreditation (Complete Sections I – J) and indicate which of the following organization(s) your laboratory is accredited by for CLIA purposes, or for which you have applied for accreditation for CLIA purposes.

The Joint Commission  AAHHSHNAP  AABB  AZLA

CAP  COLA  ASH

If you are applying for a Certificate of Accreditation, you must provide evidence of accreditation for your laboratory by an approved accreditation organization as listed above for CLIA purposes or evidence of application for such accreditation within 11 months after receipt of your Certificate of Registration.

NOTE: Laboratory director performing non-waived testing (including PPMP) must meet specific education, training and experience under subject M of the CLIA regulations. Proof of these qualifications for the laboratory director must be submitted with this application.

**PIA Disclosure Statement**  
According to the Privacy Policy Act of 1974, we prepare an annual report to a collection of information about it (display a valid CMS control number). We will use this control number for the information collection (0938-0161). Expiration Date: 09/30/21. The time required to complete this information collection is estimated to average one hour per response, including the time to review instructions, search existing data sources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of these estimates or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attention: PRA Reports Clearance Office, Mail Stop C9-30-05, Baltimore, Maryland 21244-1802. \*\*\*\*\*  
DISCLAIMER: Please do not send applications, claims, payments, medical records or any documents containing sensitive information to the PRA Reports Clearance Office. Please note that any correspondence not pertaining to the information collection burden approved under the associated CMS control number listed on this form will not be reviewed, forwarded, or returned. If you have questions or concerns regarding where to submit your documents, please contact [1-800-453-3045](mailto:1-800-453-3045).

Form CMS-116-09/20



### 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.*

# Current Statistics

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

Source: CMS database - October 2020

# Current Statistics

<b>Total Number of New CLIA Laboratories since March 2020</b>	<b>17,098</b>
• 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

# 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.

# 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%
<b>Total</b>	<b>11</b>	<b>1</b>	<b>20</b>	<b>118</b>	<b>1</b>	<b>5</b>	<b>3</b>	<b>17</b>	<b>11</b>	<b>3</b>	<b>190</b>

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/suscriber/new?topic\\_id=USCMS\\_12461](https://public.govdelivery.com/accounts/USCMS/suscriber/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](#).

- 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 1<sup>st</sup> 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](#)

# Contact Information

Contact CMS at

[LabExcellence@cms.hhs.gov](mailto:LabExcellence@cms.hhs.gov)

If inquiry is specific to the IFC,  
add “**CMS-3401-IFC**” in the subject header

Thank You!!