



Clinical Laboratory Registration Procedure

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Purpose To describe the requirements and processes to obtain certification and licensure for the Clinical Laboratory Improvement Amendment (CLIA) Certificate of Waiver (CoW) through the United States Health and Human Services (HHS) Centers for Medicare and Medicaid Services (CMS), and the State Clinical Laboratory Registration (SCLR) through the California Department of Public Health (CDPH).

Overview In compliance with CLIA, CMS certifies clinical laboratories to conduct different levels of testing including waived tests, moderate complexity tests, and high complexity tests. Clinical laboratories that conduct only waived tests receive a CLIA CoW. Designated DBH clinics will obtain a CLIA CoW to conduct onsite waived tests such as urine screenings, blood glucose testing, and alcohol detection. The CLIA CoW informs CDPH that CMS authorizes DBH to conduct waived laboratory testing so that CDPH knows DBH laboratories need to be registered, not licensed.

New Online Application The applications for CLIA CoW and California SCLR are submitted online through the CDPH website. The table below describes the steps and actions to submit application and SCLR fees online:

STEP	ACTION
1	Assigned DBH staff navigate to CDPH website's application page: https://www.cdph.ca.gov/Programs/OSPHLD/LFS/Pages/OnlineNewApplication.aspx
2	Read all information on this webpage before proceeding paying careful attention to notes, and steps 1-3
3	Create or log into existing account
4	CDPH system creates the forms that need to be signed and dated
5	San Bernardino County Chief Executive Officer (County CEO) and the designated DBH Laboratory Director review, approve, sign, and date required documentation for each laboratory. (Refer to <i>Required Forms</i> block)
6	DBH staff uploads signed documentation
7	SCLR fee is paid electronically (Refer to <i>Payment</i> block)
8	Application is submitted electronically by DBH staff once all documentation and the fee payment are recorded in the system

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Clinical Laboratory Registration Procedure, Continued

New Online Application, continued

For additional information on how to use the online system for a new application and to find the user manual please refer to:
<https://www.cdph.ca.gov/Programs/OSPHLD/LFS/Pages/OnlineNewApplication.aspx>

To create a user account with CDPH (approval from Program Manager is required) refer to: <https://accountportal.cdph.ca.gov/licensing.aspx>.

For portal to access CDPH Certificates, Licenses, Permits, and Registrations for authorized users refer to:
https://mylicense.cdph.ca.gov/prweb/PRWebLDAP1/app/default/JNjzDdEndczmljcX8iwY6FVR4wsiXbPN1fW1kioTBJ4*!STANDARD

Required Forms

The table below identifies the forms required by CMS and CDPH for the CLIA CoW application:

Form Number	Form Name	Required Actions
CMS 116	Clinical Laboratory Improvement Amendments (CLIA) Application for Certification	<ul style="list-style-type: none"> Assigned DBH Staff fully completes the application. Laboratory Director signs and dates the application (this can be done electronically). Payment for this application will be invoiced by CMS later.
LAB 155	Application for Initial Clinical Laboratory Registration	<ul style="list-style-type: none"> Assigned DBH Staff fully completes the application. Laboratory Director and County CEO sign and date the application (this can be done electronically). Payment must be submitted to CDPH with this application.

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Clinical Laboratory Registration Procedure, Continued

Required Forms, continued

Form Number	Form Name	Required Actions
LAB 182	Owner's Attestation	<ul style="list-style-type: none"> Assigned DBH Staff fully completes the form. County CEO signs and dates the form (this can be done electronically).
LAB 183	Laboratory Director's Attestation	<ul style="list-style-type: none"> Assigned DBH Staff fully completes the form. Laboratory Director signs and dates the form (this can be done electronically).

Fee Schedules

For the current fee schedule and any additional information regarding CMS (CLIA CoW) fees please refer to:
https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/clia_certificate_fee_schedule.pdf.

For the current California SCLR fee schedule please refer to:
<https://www.cdph.ca.gov/Programs/OSPHLD/LFS/Pages/Fees.aspx>

Payments

Fees shall be paid electronically using a Cal-Card. Assigned DBH staff with access to a Cal-Card shall obtain approval from Program Manager and/or Deputy Director prior to making payments.

Fees for the CLIA CoW shall be paid upon receipt of invoice from CMS. Pay the CLIA Laboratory User Fee online at Direct Pay.gov link: <https://pay.gov/public/form/start/55598674>. Continue to form and follow prompts.

Fees for the California SCLR are paid online during the application process. The table below describes the steps and actions to make payment:

STEP	ACTION
1	Assigned DBH staff with access to an authorized Cal-Card requests approval for use from Program Manager and/or Deputy Director.
2	Once approval is received, assigned DBH Staff logs into the previously authorized CDPH Account.
3	Select the pending application that needs to be paid.
4	Click Shopping Cart.
5	Click Proceed to Checkout.

Clinical Laboratory Registration Procedure, Continued

Payments, continued

STEP	ACTION
6	Select the item to be included in the transaction.
7	Enter payment details and check the payment authorization clause.
8	Click Submit.

A record of the payment fee will be posted on the application.

Renewal of CLIA CoW

The CLIA CoW must be renewed biennially. CMS currently mails a CLIA Laboratory User Fee Invoice with the CLIA number to the address of record six (6) months in advance of current CLIA CoW expiration date.

DBH shall track expiration dates to ensure renewals are made timely to avoid additional late fees, and possible termination of CLIA CoW.

Pay CLIA Laboratory User Fee online at Direct Pay.gov link: <https://pay.gov/public/form/start/55598674>. Continue to form and follow prompts.

Renewal of California SCLR

The California SCLR must be renewed annually. CDPH currently mails a renewal notice to the address of record 75 days in advance of current SCLR's expiration date.

DBH shall track expiration dates to ensure renewals are made timely to avoid additional late fees and possible termination of SCLR and CLIA CoW.

The table below identifies the forms required to renew a SCLR:

Form Number	Form Name	Required Actions
LAB 182	Owner's Attestation	<ul style="list-style-type: none"> Assigned DBH Staff fully completes the form. County CEO signs and dates the form (this can be done electronically).
LAB 183	Laboratory Director's Attestation	<ul style="list-style-type: none"> Assigned DBH Staff fully completes the form. Laboratory Director signs and dates the form (this can be done electronically).

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Clinical Laboratory Registration Procedure, Continued

Renewal of California SCLR, continued

Form Number	Form Name	Required Actions
CMS 116	Clinical Laboratory Improvement Amendments (CLIA) Application for Certification	<ul style="list-style-type: none"> • This form is only required if there are changes. • Assigned DBH Staff fully completes the application. • Laboratory Director signs and dates the application (this can be done electronically).

SCLR renewal fees are paid online on the CDPH website's Clinical and Public Health Laboratories page:
<https://www.cdph.ca.gov/Programs/OSPHLD/LFS/Pages/ClinicalandPublicHealthLaboratories.aspx>

Online Renewal of California SCLR

The table below describes the steps and actions to renew California SCLR online:

STEP	ACTION
1	Assigned DBH staff logs into the previously authorized CDPH <u>Account</u> .
2	Find site identified on the renewal notice and click <i>Link Site</i> .
3	On the welcome screen, click the business to find the testing site to renew and click the <i>Continue</i> button to begin the renewal.
4	Assigned DBH staff completes the required information online.
5	CDPH system creates the forms that need to be signed and dated.
6	County CEO and Laboratory Director review, approve, sign, and date required documentation.
7	DBH staff uploads signed documentation.
8	Fee is submitted electronically.
9	Application will be submitted electronically by DBH staff once all the documentation and fee payment are recorded in the system.

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Clinical Laboratory Registration Procedure, Continued

Online Renewal of California SCLR, continued

Reminders:

- Do not start a new application.
- Do not submit an online renewal if the renewal was already mailed.
- Late renewals require additional late fee therefore renewals shall be submitted at least 60 days prior to the expiration date to avoid termination of the CLIA License.
- To reapply following termination of the CLIA license a new application must be submitted.

For additional information on how to use the online system for a renewal and to find the user manual please refer to:

<https://www.cdph.ca.gov/Programs/OSPHLD/LFS/Pages/Renew.aspx>.

Who to Contact with Questions

For questions regarding applications, renewals, or payments for CLIA COW or California SCLR please contact:

California Department of Public Health
Division of Laboratory Science Laboratory Field Services
320 W 4th St Ste 890
Los Angeles, CA 90013-2398
(213) 620-6160 FAX: (213) 620-6565
Email: LFSCCLIA@cdph.ca

Posting CLIA Certificate and Registration

CLIA CoW and SCLR shall be visibly posted in the DBH clinic where the DBH laboratory is in operation. DBH will monitor for adherence to this requirement.

Related Policy or Procedure

[DBH Standard Practice Manual:](#)

- Laboratory Services/Physical Assessment Policy (MDS2019)
 - Laboratory Services/Physical Assessment Procedure (MDS2019-1)
 - Clinical Practice Guidelines for the Management of Substance Use Disorders 2020
 - Clinical Laboratory Registration Policy (MDS2033)
 - Clinical Laboratory Onsite Testing Procedure (MDS2033-2)
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Reference(s)

United States Department of Health and Human Services Centers for Medicare and Medicaid Services (How to Obtain a CLIA Certificate through CMS)

- <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/downloads/HowObtainCLIACertificate.pdf>
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