

CLIA CORNER

State Hygienic Laboratory at The University of Iowa

First Quarter 2024

In This Issue...

- Increase in CLIA fees;
- Explanation of the CLIA fee process; and
- Option to receive electronic certificates and certificate fees



Effective 01/27/2024, the Centers for Medicare & Medicaid Services (CMS) increased CLIA fees and will start charging for additional survey activities. The increase in fees is needed to provide sustainable funding for the CLIA program which is a user fee-funded program.

Certificate of Waiver (CoW) & Certificate for Provider-Performed Microscopy Procedures (PPMP)

For Certificates of Waiver (CoW) and Certificates of Provider Performed Microscopy Procedures (PPMP), there is one CLIA certificate fee. When a laboratory applies for either a CoW or PPMP, it receives a certificate fee. When the certificate fee is paid, the new certificate is generated and mailed (either physically or electronically).

Six months prior to the expiration date of the CoW or PPMP, a renewal fee invoice is automatically generated and sent. As long as payment posts to the laboratory's account, the certificate is automatically renewed and a new certificate is mailed (either physically or electronically) one month prior to the current expiration date. **NEW:** CMS previously sent a total of three renewal fee invoices; CMS will now only send two. If payment is not posted to the laboratory's account by the certificate expiration date, the certificate will be terminated for non-payment.

Certificate of Registration (CoR)

When a laboratory first applies for a Certificate of Accreditation (CoA), Certificate of Compliance (CoC), or switches to either a CoA or CoC, there is a one-time CoR fee. After the CoR fee is paid, the certificate is generated and mailed (either physically or electronically). The CoR acts as a temporary certificate and allows the laboratory to perform non-waived testing prior to being surveyed by either an accreditation organization (AO) or the CLIA State Agency (SA). In addition to the CoR fee, the facility will have additional fees depending on whether they have a CoA or CoC. See these specific certificate types below for an explanation of additional fees.

Certificate of Accreditation (CoA)

When a laboratory first applies for a CoA and pays the necessary CoR fee, the laboratory receives a CoR. The AO performs an initial survey within a year of the effective date of the CoR. After the survey, the laboratory is charged a certificate fee and a validation

survey fee (there are two fees but only one bill.) The validation survey fee is 5% of the CLIA compliance fees (see fee schedule on page 3). Annually, each CLIA SA must perform a specific number of validation surveys. This is to ensure the AO's standards meet or exceed the CLIA requirements. The validation survey fee is used to fund the performance of the validation surveys. Once the certificate/validation survey fee is paid, the new CoA is generated and mailed (either physically or electronically).

II. TYPE OF CERTIFICATE REQUESTED (Check only one) Please refer to the accompanying instructions for inspection and certificate testing requirements)			
<input type="checkbox"/> Certificate of Waiver (Complete Sections I – VI and IX – X)			
NOTE: Laboratory directors performing non-waived testing (including PPM) must meet specific education, training and experience under subpart M of the CLIA regulations. Proof of these qualifications for the laboratory director must be submitted with this application.			
<input type="checkbox"/> Certificate for Provider Performed Microscopy Procedures (PPM) (Complete Sections I-VII and IX-X)			
<input type="checkbox"/> Certificate of Compliance (Complete Sections I – X)			
<input type="checkbox"/> Certificate of Accreditation (Complete Sections I – X) 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.			
<input type="checkbox"/> The Joint Commission	<input type="checkbox"/> ACHC	<input type="checkbox"/> AABB	<input type="checkbox"/> A2LA
<input type="checkbox"/> CAP	<input type="checkbox"/> COLA	<input type="checkbox"/> ASHI	

Certificate of Accreditation (CoA) continued:

Six months prior to the expiration date of the CoA, a renewal fee is automatically generated. The renewal fee consists of the certificate fee plus the validation survey fee (5% of the CLIA compliance fee). As long as payment posts to the laboratory's account, the new certificate is mailed (either physically or electronically) one month prior to the expiration date. **NEW:** CMS previously sent a total of three renewal fee invoices; CMS will now only send two. If payment is not posted to the laboratory's account by the certificate expiration date, the certificate will be terminated for non-payment.

Certificate of Compliance (CoC)







When a laboratory first applies for a CoC, it receives one bill with two fees; the CoR fee plus a compliance fee. The compliance fee is the survey fee. When payment posts to the laboratory's account, it receives its new CoR and testing may begin. The initial CLIA survey takes place about three to six months after the date that non-waived testing began. All initial surveys must be completed within one year of the CoR effective date. After the CLIA survey is performed and an acceptable plan of correction or allegation of compliance is submitted (if necessary), a certificate fee is generated. Once payment of the certificate fee posts to the laboratory's account, the new CoC is mailed (either physically or electronically).

For a CoC renewal, there are always two fees and two bills. One year prior to the expiration date of the CoC, a compliance (survey) fee is automatically generated and sent to the facility. It must be paid before the recertification survey can be performed. Once the CLIA survey is performed and an acceptable plan of correction or allegation of compliance is received (if necessary), a certificate fee is generated. As long as payment posts to the laboratory's account, the new certificate is mailed one month prior to the expiration date. **NEW:** CMS previously sent a total of three renewal fee invoices; CMS will now only send two. If payment is not posted to the laboratory's account by the certificate expiration date, the certificate will be terminated for non-payment.

The fee process described above has not changed, however, effective 01/27/2024, the amount of the fees increased. The CoW , PPMP, and CoR certificates have a flat fee. For CoA and CoC certificates, the compliance, validation and certificate fees are based upon the number of specialties performed by the facility AND the volume of testing. The certificate fee amounts are consistent for all laboratories, however, the compliance (survey) fee varies per state. Contact your [State Agency](#) for further information about state specific compliance (survey) fees.

Additional CLIA fees

Effective 01/27/2024, the CLIA program implemented additional fees for the following scenarios:

-  **Onsite follow-up survey:** These surveys are performed to determine if deficient practices found during validation surveys (CoA) and/or CLIA (CoC) surveys have been corrected. A fee will be charged for the additional on-site survey.
-  **Addition of specialties survey:** When a laboratory adds a new specialty (non-waived testing not previously performed) to its' CoC, an addition of specialties survey may be performed to review the new testing if the laboratory does not have a planned survey within six months. A fee will be charged for the additional on-site survey.
-  **Substantiated complaint survey:** Complaint surveys are unannounced and performed by the SA. If, during the survey, the complaint against the laboratory is found to be substantiated, the laboratory will be charged a fee.
-  **Unsuccessful proficiency testing (PT) desk review survey:** Every 30 – 45 days, the SA pulls a report which shows laboratories that have received unsuccessful PT scores for regulated analytes, specialties, and subspecialties. If the laboratory has an initial or non-initial PT failure for the same regulated analyte, specialty, or subspecialty, the SA performs a PT desk review survey. A fee will be charged for these surveys.
-  **Replacement certificates:** If a laboratory loses its certificate or it is destroyed and the laboratory requests a replacement certificate (with no changes to the certificate type or demographic information), a replacement certificate fee will be charged.
-  **Revised certificates:** If a facility changes demographic information such as a facility name, address, or laboratory director AND they request a new certificate be printed documenting the new information, the facility will be charged a revised certificate fee.

If the laboratory fails to submit payment for the additional survey fees described above, the CLIA certificate will be terminated for non-payment.

New Certificate and Compliance Fees

Type of Laboratory	Number of Specialties	Annual Test Volume	Registration (One Time) Fee	Biennial Certificate Fee	CMS Compliance (Survey) Fee Iowa
Waived	N/A	N/A	N/A	\$248	N/A
PPM	N/A	N/A	N/A	\$297	N/A
Low Volume V	N/A	Less than 2,000	\$123	\$223	\$445
Schedule A	3 or fewer	2,000 – 10,000	\$123	\$223	\$1406
Schedule B	4 or more	2,000 – 10,000	\$123	\$223	\$1875
Schedule C	3 or fewer	10,001- 25,000	\$123	\$639	\$2345
Schedule D	4 or more	10,001 – 25,000	\$123	\$654	\$2755
Schedule E	N/A	25,001 – 50,000	\$123	\$966	\$3165
Schedule F	N/A	50,001 – 75,000	\$123	\$1635	\$3575
Schedule G	N/A	75,001 – 100,000	\$123	\$2304	\$3985
Schedule H	N/A	100,001 – 500,000	\$123	\$3032	\$4396
Schedule I	N/A	500,001 – 1,000,000	\$123	\$9244	\$4806
Schedule J	N/A	Greater than 1,000,000	\$123	\$11,801	\$4806

***Reminder the validation fee is 5% of the compliance fee**

Replacement and Revised Certificate Fees

Certificate Type	Cost of Replacement Certificate	Cost of Revised Certificate
Certificate of Waiver	\$75	\$95
Certificate of Provider Performed Microscopy	\$75	\$150
Certificate of Registration	\$75	\$150
Certificate of Accreditation	\$75	\$95
Certificate of Compliance	\$75	\$150

Additional CLIA Fees

The fees associated with on-site revisit surveys, addition of specialty surveys, substantiated complaints, and unsuccessful PT desk review surveys will vary per laboratory. The surveyor performing these surveys will keep track of the time it takes to complete the survey from beginning to end. The laboratory will be charged a fee based upon the time it takes to complete the survey at an hourly rate of **\$111.81 per hour**.

*CMS has estimated that substantiated complaint surveys could take between 5 – 100+ hours to complete; unsuccessful PT desk review surveys could take between 1 - 32 hours to complete; and on-site revisit surveys could take between 8 – 20 hours to complete.

Electronic Fees and Electronic Certificates

CMS recently acquired the capability of emailing CLIA fee invoices and certificates. In order for a laboratory to receive an electronic copy of the CLIA fee or certificate, contact your SA and request an update to the CMS database to receive electronic notifications by email. Additionally, when completing the CMS-116 application form, include the contact email address on page 1 and check the box that states, "Receive Future Notifications via Email." This will ensure that the contact listed receives an electronic link for the fee invoices and certificate. **NOTE: It is recommended that the contact email address be one to which multiple individuals have access rather than a single individual.**

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

Form Approved
OMB No. 0938-0581

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) APPLICATION FOR CERTIFICATION

ALL APPLICABLE SECTIONS OF THIS FORM MUST BE COMPLETED.

I. GENERAL INFORMATION

<input type="checkbox"/> Initial Application Anticipated Start Date _____ <input type="checkbox"/> Survey <input type="checkbox"/> Change in Certificate Type <input type="checkbox"/> Other Changes (Specify) _____ Effective Date _____	CLIA IDENTIFICATION NUMBER _____ D _____ <i>(If an initial application leave blank, a number will be assigned)</i>
FACILITY NAME _____	FEDERAL TAX IDENTIFICATION NUMBER _____
EMAIL ADDRESS shl-clia@uiowa.edu	TELEPHONE NO. (Include area code) FAX NO. (Include area code)
<input checked="" type="checkbox"/> RECEIVE FUTURE NOTIFICATIONS VIA EMAIL	

CMS also recently started posting links to current CLIA certificates on the S&C's Quality, Certification and Oversight Report (QCOR) website. If your laboratory's certificate printed after 11/01/2023, a link to the electronic certificate is accessible on the [QCOR website](#). Enter the CLIA number for your facility in the CLIA Laboratory Lookup screen, and click search. In the next screen, click on the laboratory name. If an electronic certificate is available, a link will be located in the certificate URL field. If, however, demographic changes have been made since the issuance of the new certificate, the electronic certificate link will not be updated with the new information. For example, the laboratory had a new certificate printed on 12/01/2023. On 01/01/2024, the laboratory submitted paperwork to update the laboratory name. When viewing the laboratory's electronic certificate on the QCOR website, it will only show the information from when the certificate was originally printed on 12/01/2023. If you would like a revised certificate, contact your [State Agency](#). A revised certificate fee will be sent to the laboratory. Once payment posts to the laboratory's account, an updated certificate will be sent to the laboratory, and an updated link will appear on the QCOR website.

CLIA Laboratory Details

CLIA Identification Number: 16D222265

Facility Name: STATE HYGIENIC LABORATORY
AT THE UNIVERSITY OF IOWA

Lab Director: MICHAEL A. PENTELLA

Address: 2490 CROSSPARK ROAD
BIOMONITORING PROGRAM
CORALVILLE, IA 52241

Phone Number: 319 335-4454

Certificate Type: Compliance

Certificate Effective Date: 08/25/2023

Certificate Expiration Date: 08/24/2025

Facility Type: Public Health Laboratories

Certificate URL: <https://iqies.cms.gov/api/igan/v1/public/attachments/1690391510739-99990-CLIA-Certificate-16D222265-2023-08-25.pdf>

If you would like your name added to our CLIA Corner google group, send an email to:

Kristine-Rotzoll@uiowa.edu or Melinda-Bochmann@uiowa.edu