

State of Michigan/Department of Community Health
Bureau of Health Systems
Laboratory Improvement Section
Frequently Asked Questions
Updated: 2/17/2009

How do I renew my CLIA Certificate?

Billing coupons are mailed from the U.S. Department of Health & Human Services, Baltimore, MD. Coupons for CLIA Certificate of Waiver, Certificate of Microscopy and Certificate of Accreditation renewals will be mailed out six months prior to your current certificate expiration date. After full payment is received, your next two year certificate cycle is considered renewed.

Compliance fee coupons for CLIA Certificate of Compliance renewals are mailed out twelve months prior to your current certificate expiration date. Full payment must be received before a compliance survey will be scheduled by MDCH. Once MDCH performs the survey and determines that your laboratory is compliant with applicable CLIA regulations, a certificate fee coupon will be mailed to you. After full payment of the certificate fee is received, your next two year certificate cycle is considered renewed.

Where do I send my payment for my CLIA Certificate?

Make check payable to: CLIA Laboratory Program. Mail check to: CLIA Laboratory Program, P.O. Box 70948, Charlotte, NC 28272-0948. Write your CLIA identification number on the check, and include the billing coupon with your payment.

When will I receive my new CLIA Certificate?

Renewed CLIA certificates will be mailed approximately two weeks prior to your current expiration date if full payment of CLIA fees is received. Initial CLIA certificates will be mailed approximately two weeks after full payment of CLIA fees is received.

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How do I request changes for my CLIA Certificate?

A new **CMS-116 CLIA Application**, completed in its entirety is required for:

- All Initial Applications
- All Certificate Status Changes
- All Reactivations of CLIA Certificates
- Laboratory Director Changes for Provider Performed Microscopy Certificates and Certificates of Compliance Only

Written Notification, including the laboratory name, CLIA number, name of the laboratory director and/or owner, the changes being made and the signature of the Laboratory Director or his/her designee must be submitted for all other certificate changes including:

- Facility Name
- Facility Location
- Facility Mailing Address
- Ownership Information
- Federal Tax ID
- Specialty/Subspecialty
- Test Volume
- Telephone and Fax Number
- Multiple Site Information
- Accreditation Organization
- Voluntary Closure/Termination
- Personnel-Technical Supervisor
- Director Changes for Certificates of Waiver and Certificates of Accreditation

In lieu of written notification, a new CMS-116 application is also acceptable.

*The back of the HHS/CMS **Fee Coupon** is acceptable for the following certificate changes only:*

- Facility Name
- Facility Location
- Facility Mailing Address
- Ownership Information
- Telephone and Fax Number
- Director Changes for Certificates of Waiver

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Do not send change requests with your payment. Requests to change facility name, address, tax id, mailing address or laboratory director must be reported to MDCH within 30 days of the change. Requests to change your CLIA certificate type must be submitted on the CMS-116 CLIA Application for Certification BEFORE you perform any tests not covered under your current certificate. All change requests must be submitted to MDCH as followings:

FAX: 517-241-3354

E-mail: DCH-BHS-Lab@michigan.gov

Postal Mail:
MDCH Bureau of Health Systems
Laboratory Improvement Section
PO Box 30664
Lansing, Michigan 48909

When applying for a Certificate of Compliance or Certificate of Accreditation, what additional information/documentation is required?

Documentation of laboratory director education and training: *When submitting an application for a Certificate of Compliance or a Certificate of Accreditation, you must also submit documentation showing that the person named as laboratory director meets the regulatory education and training requirements for the level of testing performed. Please call 517-241-0821 for further information.*

Documentation of Laboratory Accreditation: *When submitting an application for a Certificate of Accreditation, you must also submit documentation showing that you have contacted the laboratory accrediting program to seek laboratory accreditation for your laboratory. Acceptable documentation includes a copy of a letter from the laboratory to the accrediting program requesting laboratory accreditation, a copy of the laboratory accreditation application submitted to the accrediting program, or a welcome letter from the accrediting program to the laboratory.*

What are the requirements to qualify as a laboratory director for a Certificate of Compliance or Certificate of Accreditation laboratory?

The regulatory education and training requirements for a laboratory director depend upon the complexity of laboratory testing performed. A state licensed physician who is board certified or board eligible in anatomic or clinical pathology meets the requirements to direct a laboratory of any complexity. All other

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individuals who wish to direct a laboratory holding a Certificate of Compliance or a Certificate of Accreditation should call 517-241-0821 for further information.

I am no longer performing laboratory testing in my office. How do I terminate my CLIA certificate?

Requests to terminate your CLIA certificate must be submitted in writing to MDCH. Include laboratory name, CLIA number, name of the laboratory director and/or owner, the reason your certificate should be terminated, the effective date of termination, your laboratory contact information and the signature of the laboratory director or his/her designee. Submit requests to:

FAX: 517-241-3354

E-mail: DCH-BHS-Lab@michigan.gov

*Postal Mail:
MDCH Bureau of Health Systems
Laboratory Improvement Section
PO Box 30664
Lansing, Michigan 48909*

What is the cost for a CLIA certificate?

Certificate of Waiver: \$150 for 2 year certificate

Certificate of Provider Performed Microscopy Procedures: \$200 for 2 year certificate

Certificate of Compliance or Certificate of Accreditation: Fees depend on the annual test volume and number of laboratory specialties/subspecialties. Call 517-241-0821 for further information.

I have a current CLIA certificate. Why did I receive a letter about laboratory licensure?

The Michigan Public Health Code requires that certain clinical laboratories located in the State be licensed. MDCH is contacting all CLIA certified laboratories located in the State to request information from them and to determine whether each laboratory must also be licensed. CLIA certification does not mean that you are licensed. Laboratories must complete the online Application for Laboratory Licensure (BHS-LAB-950) and submit the completed

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form to MDCH by the deadline stated in the letter. MDCH will contact you if your laboratory requires licensure.