

## Montana CLIA Frequently Asked Questions:

### Q: Where do I send my payment for a CLIA Certificate?

For new CLIA Certificates: A bill will be automatically generated and mailed to you within two weeks after your complete application has been entered into the computer by the CMS CLIA program. You will send payment with the return portion of your bill to: CLIA LABORATORY PROGRAM, PO BOX 530882, Atlanta, GA 30353-0882. **DO NOT SEND PAYMENT TO THE MONTANA CLIA OFFICE.** We will not forward the payment.

If you prefer *electronic* payment, you may use <https://pay.gov/> to pay online. Enter 'CLIA' in the search box and follow the instructions. This requires your new CLIA ID number which is generated when your application is entered into the computer. To find out what your CLIA number is, call 406-444-2099 after your application has been entered into the computer and ask for the new CLIA number for your facility. Have the facility name and tax ID number ready for identity verification.

For existing CLIA Certificates: A bill will be automatically generated and mailed to you 1 year prior to the expiration date of your certificate. Return the bottom portion of your bill with your payment to: CLIA LABORATORY PROGRAM, PO BOX 530882, Atlanta, GA 30353-0882. **DO NOT SEND PAYMENT TO THE MONTANA CLIA OFFICE.** We will not forward your payment.

If you prefer *electronic* payment, you may use <https://pay.gov/> to pay online. Enter 'CLIA' in the search box and follow the instructions. Have your CLIA number ready.

### Q: Can I pay for my CLIA certificate online?

A: Yes. If you prefer *electronic* payment, you may use <https://pay.gov/> to pay online for your CLIA certificate. Enter 'CLIA' in the search box and follow the instructions. Have your CLIA number ready.

### Q: When will my bill show up?

A: Bills for existing CLIA certificates are automatically printed and mailed 1 year prior to your CLIA certificate expiration date. Make sure any changes to your mailing address are up to date with the Montana CLIA Program. Written notice is required for all address updates. You may send your updates via email ([mtssad@mt.gov](mailto:mtssad@mt.gov)), fax (406-444-3456), or mail (Certification Bureau-CLIA Program, 2<sup>nd</sup> floor DPHHS-QAD, PO BOX 202953, Helena, MT 59620-2953).

### Q: Where is my CLIA certificate?

A: If you have paid for your new CLIA certificate, your certificate will be automatically printed and mailed during the month prior to the expiration of your current certificate. Do not expect the certificate earlier than 1 month prior to the expiration on your current certificate.

### Q: I lost my certificate. How do I get a new one?

A: New certificates are not printed to replace lost certificates. You may contact the Montana CLIA Program (at 406-444-2099 or at [mtssad@mt.gov](mailto:mtssad@mt.gov)) to get an official Letter of Verification which will verify to all official parties that you have a current, valid CLIA certificate. Please be ready to provide your CLIA

number and your tax ID number for identity verification. You will get a new certificate again for the next 2 year cycle.

**Q: I changed my laboratory director. What do I need to do?**

A: Changes in laboratory director must be communicated to the Montana CLIA Program within 30 days in writing by completely filling out a CMS-116 form. The CMS-116 form can be downloaded at [www.cms.gov/CLIA](http://www.cms.gov/CLIA) under the “How to Apply for a CLIA Certificate, Including International Laboratories” tab on the left side of the screen. Scroll to the bottom of the page for the link to the CMS-116 application. Incomplete CMS-116 forms cannot be entered. You may send the completed CMS-116 via fax (406-444-3456), email ([mtssad@mt.gov](mailto:mtssad@mt.gov)), or mail (Certification Bureau-CLIA Program, 2<sup>nd</sup> floor DPHHS-QAD, PO BOX 202953, Helena, MT 59620-2953).

**Q: Where can I find the CMS-116 form?**

A: The CMS-116 form can be downloaded at [www.cms.gov/CLIA](http://www.cms.gov/CLIA) under the “How to Apply for a CLIA Certificate, Including International Laboratories” tab on the left side of the screen. Scroll to the bottom of the page for the link to the CMS-116 application. Incomplete CMS-116 forms cannot be entered. You may send the completed CMS-116 via fax (406-444-3456), email ([mtssad@mt.gov](mailto:mtssad@mt.gov)), or mail (Certification Bureau-CLIA Program, 2<sup>nd</sup> floor DPHHS-QAD, PO BOX 202953, Helena, MT 59620-2953). The newest version of the CMS-116 form is required.

**Q: Where do I find additional CLIA information?**

A: [www.cms.gov/CLIA](http://www.cms.gov/CLIA)

**Q: Can a patient order laboratory tests without a doctor’s order? What are the Montana laws regarding Direct Access Testing?**

A: CLIA in the state of Montana does not regulate who can order tests. Each facility must decide the facility policy on who it will accept test orders from. However, most insurance agencies will only pay for physician ordered tests and will not pay for self-ordered tests. Direct Access Testing (DAT) refers to a patient ordering laboratory tests without prior consultation from a physician for testing. Some states have written laws that require a physician to order laboratory tests. Montana does not currently require a physician to order tests. Facility policies determine how Direct Access Testing is handled by the facility.

**Q: What are Montana’s laws regarding laboratory specimens drawn in the state of Montana but sent to another state for testing?**

A: Laboratory specimens may be drawn/collected in the state of Montana and sent to an out-of-state facility for testing without a Montana CLIA license. The facility performing the laboratory testing MUST have a CLIA license for the state in which they are operating and provide that CLIA number to each facility drawing specimens in Montana per the federal CLIA regulations.

Note: Any facility performing laboratory testing in Montana **MUST** have a Montana CLIA license.

**Q: How do I get a Montana CLIA Certificate?**

A: You must fill out a CMS-116 application which can be downloaded from [www.cms.gov/CLIA](http://www.cms.gov/CLIA). Return the completed CMS-116 form to the Montana CLIA Program via fax (406-444-3456), email ([mtssad@mt.gov](mailto:mtssad@mt.gov)), or mail (Certification Bureau-CLIA Program, 2<sup>nd</sup> floor DPHHS-QAD, PO BOX 202953, Helena, MT 59620-2953). A bill will be automatically generated and mailed to you within two weeks after your application has been entered into the computer by the CLIA program. You will send payment with the bottom portion of your bill to: CLIA LABORATORY PROGRAM, PO BOX 530882, Atlanta, GA 30353-0882. DO NOT SEND PAYMENT TO THE MONTANA CLIA OFFICE.

If you prefer *electronic* payment, you may use <https://pay.gov/> to pay online. Enter 'CLIA' in the search box and follow the instructions. This requires your new CLIA ID number which is generated when your application is entered into the computer. To find out what your CLIA number is, call 406-444-2099 after your application has been entered into the computer and ask for the new CLIA number for your facility. Have the facility name and tax ID number ready for identity verification.

**Q: Where do I find individual licensing information?**

A: Licensing is through the Montana Board of Clinical Laboratory Science Practitioners.

The link to that site is:

[http://bsd.dli.mt.gov/license/bsd\\_boards/cls\\_board/board\\_page.asp](http://bsd.dli.mt.gov/license/bsd_boards/cls_board/board_page.asp)

**Q: What do I need to know for a Certificate of Waiver?**

A: The following website has information regarding a Certificate of Waiver:

[http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Certificate\\_of\\_Waiver\\_Laboratory\\_Project.html](http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Certificate_of_Waiver_Laboratory_Project.html)

**Q: How do I change to a different certificate type?**

A: To change to different certificate type, you must fill out a new CMS-116 form (downloadable from [www.cms.gov/CLIA](http://www.cms.gov/CLIA)) and submit it to the Montana CLIA Program (fax: 406-444-3456, email: [mtssad@mt.gov](mailto:mtssad@mt.gov), or mail at Certification Bureau, PO Box 202953, Helena, MT 59620). Please indicate that it is a change in the certificate at the top. If you are changing to a PPMP or to a compliance certificate, you must also provide the credentials for the laboratory director to the Montana CLIA Program for review before the change can be processed. For the required qualifications to be a lab director for these certificates, please see [www.cms.gov/CLIA](http://www.cms.gov/CLIA).

**Q: How long does a Certificate last?**

A: All certificates last for two years. Renewal notices will be sent out starting one year prior to the certificate expiration date.

**Q: I have more questions that were not answered here. Where can I find the answers?**

A: You will find a lot of necessary information at [www.cms.gov/CLIA](http://www.cms.gov/CLIA). If you still have questions, contact the Montana CLIA Program at 406-444-2099 or [mtssad@mt.gov](mailto:mtssad@mt.gov).