



Important Notice about CMS Bills, CLIA Certificates, and COLA Accreditation

COLA participants **are required** to obtain a two-year Certificate of Accreditation from CMS and to pay a validation inspection fee to CMS. The cost of the certificate depends on the volume of testing and the number of specialties performed in the laboratory.

The validation inspection fee appears on your biennial CMS bill in the same location as the charge would be for a full inspection by the state CLIA agency. This is not a charge for a full inspection by the state CLIA agency, but a fee charged to all accredited labs to offset the cost of government inspections required to validate the accreditation process. The fee is five percent of what the laboratory's inspection would have been, if it were in the government inspection program with the state CLIA agency. Approximately **five percent** of all accredited labs are selected to undergo an onsite validation inspection.

You must always pay your biennial CMS fees (including the validation fee) in order to renew your CLIA certificate. COLA biennial accreditation fees are separate and must also be paid.

COLA accreditation is approved by the federal government for CLIA purposes, and therefore COLA participants are not required to pay the full CMS biennial inspection fee. If a COLA-accredited laboratory receives a bill for a full inspection from CMS, this generally means that the laboratory has a Certificate of Compliance instead of the Certificate of Accreditation that is required for an accredited laboratory. If your COLA-accredited laboratory receives a full government inspection fee from CMS, the laboratory should NOT pay it, but rather notify your state CLIA agency in writing that the laboratory is enrolled with COLA. **The written notification must include:**

- A completed CMS 116 form requesting the change to a Certificate of Accreditation
- A copy of the COLA Verification of Enrollment letter.

Download the CMS 116 form at: <http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms116.pdf>.

A list of state CLIA agency contacts can be found at:

<http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf>.

It is critical that you use the CMS 116 form to apply to switch your CLIA certificate type to a Certificate of Accreditation, with COLA as your accrediting organization.

- A laboratory with a Certificate of Waiver, Provider Performed Microscopy Certificate, or a Certificate of Compliance is charged a \$100 switching fee. Once the fee is paid, the laboratory receives its Certificate of Registration for Accreditation.
- A laboratory that already has a Certificate of Accreditation, does not pay a fee, but must submit the CMS 116 form to notify the CMS state agency that they are switching to another accrediting agency.
- A laboratory receives their CMS Certificate of Accreditation after being inspected by COLA and paying the biennial CMS fee for the Certificate of Accreditation.

If you have any questions, please contact COLA at 800-981-9883.