Clinical Laboratory Improvement Amendment Information

Overview of Requirements

The Clinical Laboratory Improvement Amendment (CLIA), a federal government program, requires a CLIA certificate when providers conduct any tests, including waived tests, on materials taken from the human body (saliva, serum, blood, urine, tissues, etc.) to provide health information for the diagnosis, prevention, or treatment of disease or impairment, or assessment of a person's health. The type of CLIA certificate required depends upon the level of complexity of the tests.

Application Process

Complete the application and email or mail it to the Minnesota Department of Health. Approximately two weeks after the application is processed, an invoice for $180 will be mailed to the provider/laboratory. The certificate will be mailed after payment is received and posted by CLIA. **Do not send payment with the application.**

CLIA Application for Certification (www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms116.pdf)

Certificates must be renewed every two years. Providers must update the CLIA Program at the Minnesota Department of Health when there are changes (such as the named laboratory director).

Certificates of Waiver

Some providers conducting tests will need a certificate of waiver. Examples of waived tests include blood glucose, fecal occult blood, streptococcus, influenza, mononucleosis, urine pregnancy, cholesterol tests and INR. Providers should review the information on the CMS CLIA website (www.cms.gov/regulations-and-guidance/legislation/clia) to determine the level of certificate, if any, that is required for their agency.

Send Completed Applications to:

CLIA Program
Minnesota Department of Health
3333 West Division Street, Suite 212
Phone 651-201-4120
St. Cloud, MN 56301
Health.clia@state.mn.us

06/30/2021

To obtain this information in a different format, call: 651-201-4200.