October 2019

CLIA update

Healthy Blue has updated our process for *Clinical Laboratory Improvement Amendments of 1988* (*CLIA*) certification validation. Our system now reads directly from the CMS Provider of Service (POS) *CLIA* file to validate *CLIA* information. CMS updates this file every three months. To ensure your claims process correctly and the POS files are current, we strongly advise that providers proactively submit an updated *CLIA* certificate three months prior to the *CLIA* certification expiration date.

The *CLIA* regulations include federal standards applicable to all U.S. facilities or sites that test human specimens for health assessment, or to diagnose, prevent or treat disease. CMS regulates all laboratory services and testing performed on humans in the U.S.

Healthy Blue providers may bill for laboratory services covered by Healthy Louisiana. To ensure proper payment, Healthy Blue will apply a *CLIA* claim edit to all claims for laboratory services that require a *CLIA* certification.

CLIA requirements for entities that perform laboratory tests
All entities that perform lab tests must meet federal requirements, including waived tests on materials derived from the human body for the purpose of providing information for a diagnosis or the assessment of human health. If an entity performs tests for these purposes, *CLIA* considers the entity a laboratory and requires the entity to register with the *CLIA* program by completing the *Clinical Laboratory Improvement Amendments of 1988 Application for Certification Form* (*CMS-116*). Upon completion of registration, the entity will be assigned a *CLIA* certification number.

The *CLIA* form and additional information can be found **here**.

Claim submission requirements
Effective for dates of service on or after August 1, 2019, professional service and independent laboratory providers are required to include a valid *CLIA* number on all claims submitted for laboratory services, including *CLIA*-waived tests. Although providers are not *currently* required to submit the *CLIA* number on the claim, Healthy Blue encourages providers to begin submitting *CLIA* numbers on claims immediately.
- Place the *CLIA* certification number in Box 23 of the *CMS-1500* claim form or in the 2300 loop of an electronically billed claim form
  - Example of valid *CLIA* number format: 19DXXXXXXX
    - The first three characters are the two-digit state code followed by the letter D.
    - The remaining seven digits are the unique *CLIA* system number assigned to the provider.
  - Example of unacceptable format: *CLIA*: 19DXXXXXXX, *CLIA* 19DXXXXXXX.
    - Do not add the letters *CLIA* or *CLIA* to the ten character *CLIA* number.
  - The *CLIA* number is not required for UB-04 claims.

- Either the servicing or the billing address on the claim should match the *CLIA* certificate address on the CMS POS file.
  - If neither address matches the address on the CMS POS file, then the claim will deny.
- The laboratory services rendered should be appropriate for the certificate level of the *CLIA* number indicated on the claim.
  - If the *CLIA* level does not allow billing for the laboratory services rendered, then the claim will deny.
- The *CLIA* number must be active on the most recent CMS POS file on the date the services were rendered.
  - If the *CLIA* number is not active on the most recent CMS POS file, then the claim will deny.
    - Healthy Blue strongly encourages providers to update *CLIA* certification expiration information at least three months prior to the *CLIA* certificate expiration date.
    - Healthy Blue uses the most recent CMS POS file to confirm *CLIA* validity and *CLIA* levels. If your *CLIA* certificate is renewed after the posting of the CMS POS file, then claims will deny until the *CLIA* certificate is listed as active on the next CMS Provider of Services file.
- *CLIA Waiver* certificates and provider-performed microscopy certificates require providers to bill a QW modifier for specific laboratory services, as indicated on the *CMS CLIA Waived Tests* list.
  - If the CMS *CLIA Waived Test* list indicates that a QW modifier is required and a QW modifier is not billed, then the claim will deny.

If you have questions about this communication or need assistance with any other item, contact your local Provider Relations representative or call Provider Services at **1-844-521-6942**.