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12/10/2019

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Aetna Better Health® of Texas
Clinical Laboratory Improvement Amendments (CLIA) requirements on Claim Submissions

Dear Provider:

Effective 1/10/2020, Aetna Better Health of Texas will require CLIA ID to be submitted on CMS 1500 claim (electronic and paper) for laboratory services.

Per Texas Medicaid Provider Procedures Manual, all Medicaid providers (in or out-of-network) must submit a valid CLIA ID on the claim in order to be reimbursed for laboratory services.

Background on CLIA

The Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA)[1]. CLIA regulations set standards that are designed to improve quality in all laboratory testing and include specifications for quality control (QC), quality assurance (QA), patient test management, personnel, and proficiency testing.[2]

Key Definitions

Referring Laboratory	Laboratory that receives a specimen to be tested and that refers the specimen to another laboratory for performance of the laboratory test.

[1] https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index?redirect=/Clia/
[2] Texas Medicaid Provider Procedures Manual, Chapter 2 - Radiology and Laboratory Services Handbook, CLIA

Reference laboratory	Laboratory that receives a specimen from another, referring laboratory for testing and that performs the test.
Type of CLIA Certification	There are 4 types of CLIA Certificates depending on the complexity of test being performed – • Certificate of Waiver • Certificate for Provider Performed Microscopy Procedures (PPM) • Certificate of Compliance • Certificate of Accreditation
CLIA Tests	List of CPT and HCPCS codes subject to CLIA Edits. Refer to: https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/SubjecttoCLIA.pdf
Waived Test	Tests that are granted waived status under CLIA. Refer to: https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/waivetbl.pdf

CLIA Requirements on CMS 1500 Claims Submissions:

- All clinical laboratory providers (including those located in physicians' offices), regardless of location, size, or type of laboratory, must meet certain standards based on the complexity of the tests they perform. Providers must hold the appropriate CLIA certificates to perform certain tests. Texas Medicaid and Aetna Better Health of Texas follow Medicare categorization of tests for CLIA certificate holders. Refer to: The CMS website at www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Catego-rization_of_Tests.html for additional information.
- Unique CLIA ID is required for the location that performed the test. Claim submission requirements will be different based on electronic or paper billing. Table below describes all the different scenarios and where CLIA ID must be submitted:

Claim Billed (Electronic or Paper)	Does one or more tests referred to another laboratory?	Claim Submission Requirements
PAPER	NO – All services were done by the same entity and address as the billing provider	• Report CLIA ID of laboratory on CMS 1500 Field # 23 • If CLIA Certification type is - Certificate of Waiver, then for each waived test, QW must be present indicating a waived test

ELECTRONIC	NO – All services were done by the same entity and address as the billing provider	• Report CLIA ID in Loop 2300, REF02, REF01 = X4 • If CLIA Certification type is - Certificate of Waiver, then for each waived test, QW must be present indicating a waived test
PAPER	YES – one or more services were referred	• Split into 2 CMS 1500 claim forms • On 1st claim: for services that were not referred – report CLIA ID of the billing entity on CMS 1500 Field #23 • On 2nd claim: for services that were referred – report CLIA ID of the referred laboratory on CMS 1500 Field #23 • Report the referred laboratory address on field # 32 and NPI on Field 32a • If CLIA Certification type is - Certificate of Waiver, then for each waived test, QW must be present indicating a waived test
ELECTRONIC	YES – one or more services were referred	• Report CLIA ID in Loop 2300, REF02, REF01 = X4 for the referring laboratory • Report CLIA ID of the referred laboratory in Loop 2400, REF02, REF01 =F4 for each referred test • Referred test must be reported with modifier 90. • If CLIA Certification type is - Certificate of Waiver, then for each waived test, QW must be present indicating a waived test

- An independent laboratory that forwards a specimen to another laboratory (independent or hospital) may bill a handling fee (procedure code 99001) for collecting and forwarding the specimen to the other laboratory if the specimen is collected by routine venipuncture or catheterization.
- EXAMPLES (*Available on CMS website*):
    - **Paper Claim**

      A physician has ordered the ABC Laboratory to perform carcinoembryonic antigen (CEA) and hemoglobin testing for a patient. Since the ABC Laboratory is approved to perform tests only within the hematology LC level (which includes the hemoglobin test), it refers the CEA testing (which is a routine chemistry LC) to the XYZ laboratory. Result: The ABC laboratory submits a claim for the hemoglobin test and reports its CLIA number in item 23 on the CMS-1500 form. Since the ABC laboratory referred the CEA test to the XYZ laboratory to perform, the ABC laboratory (billing laboratory)

submits a second claim for the CEA testing, reporting XYZ's CLIA number in item 23 on the CMS-1500 form. The XYZ laboratory's name, address, and ZIP Code are also reported in item 32 and the NPI is reported in item 32a on Form CMS-1500 to show where the service (test) was actually rendered.

- **Electronic Claim**

  A physician has ordered the DEF independent laboratory to perform glucose testing and tissue typing for a patient. Since the DEF Laboratory is approved to perform only at the routine chemistry LC level (which includes glucose testing), it refers the tissue-typing test to the GHI laboratory.

  The DEF laboratory submits a single claim for the glucose and tissue typing tests; the line item service for the glucose test is submitted without a '90' modifier since the DEF laboratory performed this test. The CLIA number for the DEF laboratory is entered in the electronic claim in:

  Loop 2300, REF02. REF01 = X4

  On the same claim, the line item service for the tissue typing test is submitted with a '90' modifier and the referral/rendering GHI laboratory's CLIA number is entered on the electronic claim in:

  Loop 2400, REF02. REF01 = F4

  Reference Laboratory's Address: An electronic claim for laboratory testing requires the presence of the performing and billing laboratory's, name and address. The performing laboratory for a service with a line item CPT 90 modifier requires provider information for the appropriate 837 loop.

CLIA Requirements on CMS 1450 Claims Submissions:

If a hospital is billing for laboratory services, CLIA ID is not required to be submitted on the claim, however facility must have maintained current and valid CLIA Certifications on file in order to bill for laboratory services. Additionally, if an independent laboratory within the hospital is billing for laboratory services directly, those claims should be submitted on a CMS 1500.