Aetna Better Health

Clinical Laboratory Improvement Amendments (CLIA) Front End Edits:

I) CLIA Regulation Background:

The Clinical Laboratory Improvement Amendments (CLIA) regulate laboratory testing and require clinical laboratories to be certified by the Center for Medicare and Medicaid Services (CMS) before they can accept human samples for diagnostic testing. CLIA generally requires all facilities that perform even one applicable test, including waived tests, on "materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings" to meet certain Federal requirements. If a facility performs tests for these purposes, it is considered a laboratory under CLIA and generally must apply and obtain a certificate from the CLIA program that corresponds to the complexity of tests performed. Note: Washington State and New York State have special/partial exemptions for the CLIA regulations.

Three federal agencies are responsible for CLIA: The Food and Drug Administration (FDA), Center for Medicaid Services (CMS), and the Centers for Disease Control and Prevention (CDC). Each agency has a unique role in assuring quality laboratory testing.

- **FDA:** Categorizes tests based on complexity. Reviews requests for Waiver by Application. Develops rules/guidance for CLIA complexity categorization
- **CMS**: Issues laboratory certificates. Conducts inspections and enforces regulatory compliance. Publishes CLIA rules and regulations
- **CDC:** Develops technical standards and laboratory practice guidelines, including standards and guidelines for cytology. Manages the Clinical Laboratory Improvement Advisory Committee (CLIAC)

II) Lab Compliance Requirements:

https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/howobtaincliacertificate.pdf

how-obtain-CLIA-certificate.brochure (1)

CLIA generally requires all facilities that perform even one applicable test, including waived tests, on "materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings" to meet certain Federal requirements. If a facility performs tests for these purposes, it is considered a laboratory under CLIA and generally must apply and obtain a certificate from the CLIA program that corresponds to the complexity of tests performed. However, you may not need a CLIA certificate if your laboratory is located in the states of New York or Washington, as those States operate their own laboratory regulatory programs. Contact the appropriate State Agency to determine if you need a CLIA certificate

Types of Certificates:

- Certificate of Waiver (COW): Issued to a laboratory that performs only waived tests.
- Certificate for Provider-performed Microscopy (PPM) procedures: Issued to a laboratory in which a physician, midlevel practitioner or dentist performs specific microscopy procedures during the course of a patient's visit. A limited list of provider-performed microscopy procedures is included under this certificate type, which are categorized as moderate complexity testing.
- Certificate of Registration* : Issued to a laboratory to allow the laboratory to conduct nonwaived (moderate and/or high complexity) testing until the laboratory is surveyed (inspected) to determine its compliance with the CLIA regulations. Only laboratories applying for a certificate of compliance or a certificate of accreditation will receive a certificate of registration.
- Certificate of Compliance (COC): Issued to a laboratory once the State Agency or CMS surveyors conduct a survey (inspection) and determine that the laboratory is compliant with the applicable CLIA requirements. This type of certificate is issued to a laboratory that performs nonwaived (moderate and/or high complexity) testing.
- Certificate of Accreditation (COA): Issued to a laboratory on the basis of the laboratory's accreditation by an accreditation organization approved by CMS. This type of certificate is issued to a laboratory that performs nonwaived (moderate and/or high complexity) testing

Tests Not subject to CLIA Certificate:

There are some testing exceptions that do not require CLIA certification. The following exceptions to CLIA certification apply regardless of a laboratory's location:

- Any laboratory that only performs testing for forensic purposes;
- Research laboratories that test human specimens but do not report patient-specific results for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, individual patients; or
- Laboratories certified by the Substance Abuse and Mental Health Services Administration (SAMHSA), in which drug testing is performed that meets SAMHSA guidelines and regulations. However, a CLIA certificate is needed for all other testing conducted by a SAMHSA-certified laboratory.

NOTE: The purpose for which the test is conducted, not the test itself, determines whether a facility conducting testing is subject to the CLIA requirements. Testing that is used to gather evidence for legal purposes, and is not performed for purposes of clinical treatment, medical diagnosis, health assessment or disease prevention is not subject to CLIA.

State laws

(1) Except as provided in paragraph (2), nothing in this section shall be construed as affecting the power of any State to enact and enforce laws relating to the matters covered by this section to the extent that such laws are not inconsistent with this section or with the regulations issued under this section.

(2) If a State enacts laws relating to matters covered by this section which provide for requirements equal to or more stringent than the requirements of this section or than the regulations issued under this section, the Secretary may exempt clinical laboratories in that State from compliance with this section.

USCODE-2011-title42-chap6A-subchapII

III) BUSINESS REQUIREMENT:

As established above, CMS requires that certain laboratory procedures performed in a providers office (place of service 11) have an active CLIA Identifier that is active for the date of service and registered to the address where the procedure is taking place. Providers must send their CLIA ID on the claim form when these procedures are billed. The following requirements document is designed to check for the:

1. need of a CLIA ID on the claim based on quarterly CMS Code Sets (table requirements detailed within)
2. proper formatting of the 10 digit CLIA ID (per CMS & HIPAA specifications) 10 digits with Alpha Character "D" in the 3rd Byte/Position

- US Code – 2011 Title 42 Chapter 6a Part F (Page 371) Section 263a(b) Certificate requirement:

  No person may solicit or accept materials derived from the human body for laboratory examination or other procedure unless there is in effect for the laboratory a certificate issued by the Secretary under this section applicable to the category of examinations or procedures which includes such examination or procedure.

- This business requirement **does not** enforce the address registration aspect of the CLIA regulations. Address validation is being omitted because the CDC, who manages and posts the list of CLIA Identifiers and addresses online, does not always post timely and accurate CLIA Address rosters. Editing against the rosters found online will often create false claim rejections or denials and this leads to provider abrasion and increased claim adjustment rates.

- This business requirement **does not** enforce the CLIA Certification types/levels or tiers cited above.

IV) CMS File Download

The compressed files are published quarterly and publicly available online at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Laboratory-Fee-Schedule-Files
includes the Clinical Laboratory Fee Schedule (CLFS) and supporting documents for all the Calendar Years. Upon extraction, four separate files will become available, download the below csv file with the naming convention

CLABxxxxQ#.csv, a comma delimited file containing CLFS data (xxxx denote the calendar year and # denote the quarter number)

Record Layout

The column header starts from line 5 and the actual data starts from line 6

Column	Name	Comment
1	Year	Current calendar year associated with the CLFS.
2	HCPCS Code	All active CPT and alpha-numeric codes subject to the CLFS.
3	Modifier	Where modifier is shown, QW denotes a CLIA waived test.
4	Effective Date	The date for which the Clinical Lab Fee Schedule becomes effective. All codes will have a '20230101' effective date per the first quarter of the new CLFS.
5	Indicator	National or local pricing indicator.
6	Payment Rate	Payment amount associated with each HCPCS code.
7	Short Description	Short description of the applicable HCPCS code.
8	Long Description	Long description of the applicable HCPCS code.
9	Extended Long Description	Extended long description of the applicable HCPCS code.

V) Requested CLIA Database table Layout:

Above record layout plus additional audit columns (convert spaces in field names to underscores "_"). Effective_Date and Term_Date should be indexed fields when the table is designed.
This table should be accessible for the entire Aetna Better Health Medicaid Enterprise. It will be needed for CLIA editing of all inbound claims or inbound encounters.

Column	Name	Comment
1	Year	Current calendar year associated with the CLFS.
2	HCPCS_Code	All active CPT and alpha-numeric codes subject to the CLFS.
3	Modifier	Where modifier is shown, QW denotes a CLIA waived test.
4	**Effective_Date**	**Load the current quarter start date in YYYYMMDD format**
5	Indicator	National or local pricing indicator.
6	Payment_Rate	Payment amount associated with each HCPCS code.
7	Short_Description	Short description of the applicable HCPCS code.
8	Long_Description	Long description of the applicable HCPCS code.
9	Extended_Long_Description	Extended long description of the applicable HCPCS code.
10	**Term_Date**	**Current Quarter gets loaded with 20991231, last upload gets updated with last quarter end date**
11	**Insert_User**	**Insert User or Process name**
12	**Insert_Datetime**	**Insert Date Time**
13	**Update_User**	**Update User or Process name**
14	**Update_Datetime**	**Update Date Time**

CLIA Database table load

The table gets loaded with quarterly files from 2021 and forward. The effective/term dates of the files are defaulted to the respective quarter start and end in YYYYMMDD format.
Example: 2022Q2 file will be loaded with Effective date 20220401 and Term Date 20220630.
The most recent file will be loaded with a term date of 20991231.

Any new file that gets loaded there after will be loaded with a term date of 20991231 and the prior quarter files term date gets updated from 20991231 to the respective quarter end.

File Load Failure

If a file load fails, please send an email to #CLIATeam@aetna.com, remove any partially loaded data from the main table.

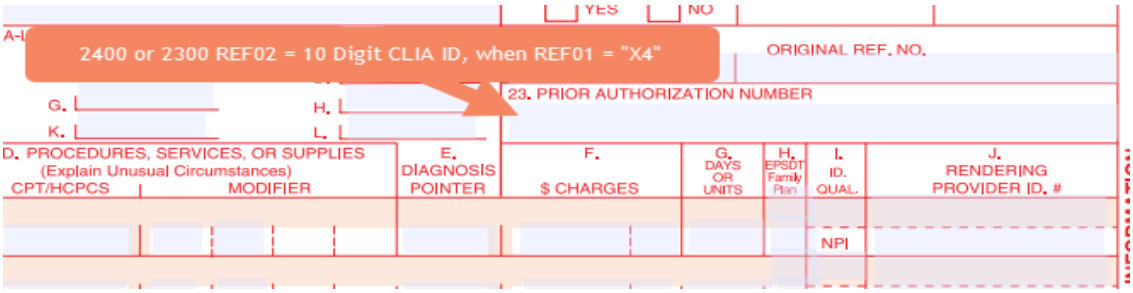
Required CLIA ID Format: CLIA# must be 10 characters in length with the letter "D" as the 3rd byte from the left.

VI) **Codes to remove from Table after Loading:** This is to prevent denial from occurring to these codes

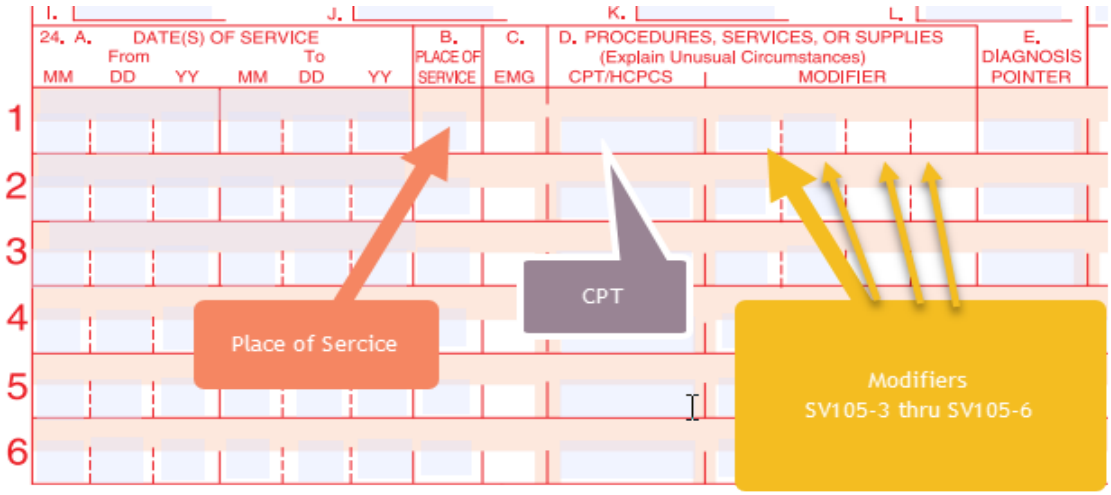
Run a Delete Records Query where CPT CODES on Table are in (36400, 36405, 36406, 36410, 36415, 36416, 36420, 36425, 83037, 82042, 82043,82270,82271, 82272, 82331, 83861, 83945, 87164, 87166, 89220, 89230, 84066, 84075, 84078, 84080, 88040, 88125, 82077, 87903, 87904, G0471, G0480, G0481, G0482, G0483, G0659, G2023, G2024, H0048, 0082U, 0227U, 0328U). Repeat this deletion step each Quarter after Quarterly update process is completed.

VII) **Relevant 837P Loops and Segments:**

- 2300 REF02 = "CLIA ID #" when 2300 REF01 = "X4" (header level)
- 2400 REF02 = "CLIA ID #" when 2400 REF01 = "X4" (line level)



- 2400 SV105 = "11" Office Place of Service (line level)
- 2300 CLM02-1 = "11" Office Place of Service (header level)
- 2400 SV101-2 = "CPT Code" when 2400 SV101-1 = HC CPT4/HCPCS Procedure
- 2400 SV101-3 = 1st Modifier Position/Box 24D CMS-1500
- 2400 SV101-4 = 2nd Modifier Position
- 2400 SV101-5 = 3rd Modifier Position
- 2400 SV101-6 = 4th Modifier Position



VIII) 837P/CMS-1500 CLIA Claim Edit Flow:

Step 1a: Does the Claim Line or Header Contain a CLIA LAB ID Indicator?
Examine 2400 REF01 = "X4" if present **else Examine 2300** REF01 = "X4"/Box23 of CMS-1500

- Yes – Go to **Step 1b**
- No – Go to **Step 2a**

Step 1b: Is the CLIA LAB ID # in the proper CMS/HIPAA format = 10 bytes with the letter "D" in the 3rd position from left)?
Examine **2400** REF02 if present, **else examine 2300** REF02 Box23 of CMS-1500

- Yes – Bypass the remained edits and proceed to normal adjudication business rules.
- No – Go to **Step 2a**

Note: QNXT Stores this in the following fields:

- saaedi_tbl_ext_edi_hcfaheader_[State].ClinicalLabImprovementNumber
- saaedi_tbl_ext_edi_hcfaservices_[State].ClinicalLabImprovementNumber

Step 2a: Was Place of Service Reported on any Claim Line in 2400 SV105/ Box 24B on CMS-1500
Note: EDI Claims may contain place of service codes on the line level, not just the header so we are looking first for line level places of service codes on the claim.

- Yes – go to **Step 2b** (when 1 or more lines contain a place of service code)
- No – go to **Step 2c.**

Note: QNXT Stores this in ClaimDetail.Location

Step 2b: Do **any** claim lines contain Place of Service Code =
"11"? Examine **2400** SV105**/**Box 24B on CMS-1500

- Yes – go to **Step 3** (when 1 or more claim lines contains POS 11)
- No – Bypass the remained edits and proceed to normal adjudication business rules.

Note: QNXT Stores this in ClaimDetail.Location

Step 2c: Does the Claim HEADER contain Place of Service Code = "11"?
Examine **2300 CLM05-1/**Box 24B on CMS-1500

- Yes – go to **Step 4**
- No – Bypass the remained edits and proceed to normal adjudication business rules.

Note: QNXT Stores this in ClaimDetail.Location
Step 3: Do the claim lines from Step 2b with POS = 11 contain CPT Codes SV101-1 = HC AND SV101-2 within ("CLIA Table") **Where** the Date of Service/DOS is between Effective_Date AND Term_Date on the table defined above.
CPT Codes SV101-1 = HC AND SV101-2/ Box 24D on CMS-1500 = CPT Code to compare to table defined above

- Yes – go to **Step 5**
- No – Bypass the remained edits and proceed to normal adjudication business rules.

Note: QNXT Stores this in ClaimDetail.ServCode

Step 4: Do **any** Claim Lines contain CPT Codes Within ("CLIA_Table") **Where** Date of Service/DOS is between Effective_Date AND Term_Date on the table defined above.
CPT Codes SV101-1 = HC AND SV101-2/ Box 24D on CMS-1500 = CPT Code to compare to table defined above

- Yes – go to **Step 5**
- No – Bypass the remained edits and proceed to normal adjudication business rules.

Note: QNXT Stores this in ClaimDetail.ServCode

Step 5: Is this a PAPER Claim?
WHERE CLAIM.PLANCRN IN ("CCF", "FVT837")

- Yes – For Each Line with CPT Codes in the Table – IT to set the line to Pending Status for manual review.
    - Claims Processor must check the image for submission of CLIA ID (Box 23 or 24 shaded)
        - If none present, Processor should Deny using codes CARC:16 and RARC:MA120
            - Memo: Denied for CLIA Proc Code and claim missing CLIA number.
        - If Present, Processor should place a note in the claim with the CLIA ID and Allow normal adjudication
- No - For Each Line with CPT Codes in the Table – set the line to deny using CARC:16 and RARC:MA120
    - Memo: Denied for CLIA Proc Code and claim missing CLIA number.

IX) Appendix:

https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/som107ap_c_labpdf.pdf

Interpretive Guidelines §493.35(b)(3) – Street Address

Common direction means that all testing sites are under one designated director. Street address is the address assigned by the Post Office and is the physical location of the laboratory. The street address may be different from the mailing address, which can be a Post Office box or a billing address. For large hospitals, such as a university campus facility, that may contain laboratories in separate buildings, consult with the RO to determine if the hospital is eligible for a single certificate.

§493.15 Laboratories Performing Waived Tests §493.15(a)

Requirement Tests for certificate of waiver must meet the descriptive criteria specified in paragraph (b) of this section.
§493.15(b) Criteria Test systems are simple laboratory examinations and procedures which:
(1) Are cleared by FDA for home use;
(2) Employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or
(3) Pose no reasonable risk of harm to the patient if the test is performed incorrectly.

To determine which tests are categorized as waived or nonwaived testing (i.e., moderate and high complexity tests), refer to the following web link for the FDA categorization database (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/Search.cfm?sAN=0). Test systems, assays and examinations not included in this listing (i.e., not yet categorized) are considered high complexity.