



Clinical Laboratory Improvement Amendment (CLIA) *Version 0.6*

Please note, all items underlined are new criteria and clarifications that have been added to the CLIA FAQ.

Frequently Asked Questions (FAQ)

1. Question: What is the deadline for Managed Care Organization (MCOs) to accommodate CLIA information using Provider Enrollment and Management System (PEMS) Master Provider File (MPF)?

Answer: The PEMS MPF has been deployed in production as of May 30, 2025. PEMS MPF contains essential information, including laboratory certification codes (CLIA Specialty and Subspecialty).

HHSC has revised the implementation timeline for making necessary changes to the MCO claim systems to accommodate the CLIA information.

- As of December 01, 2025, HHSC will provide MCOs 90 days to build a soft edit. The soft edit would not deny the CLIA claim, but it should be set up to warn and notify the provider if they bill for a procedure without appropriate CLIA certification to update their missing CLIA information in PEMS.
 - The explanation of benefits (EOB)/explanation of payment (EOP) found on the claim's remittance and status (R&S) should be updated to inform providers to update PEMS with CLIA certification. The EOB/EOP should be provider facing and should be informative and descriptive for providers to follow and update CLIA certification in PEMS.
 - A provider notification is required to inform providers about the soft edit and the upcoming hard edit. Individual provider letters are not required.

- By dates of service (DOS) March 01, 2026, HHSC will require MCOs to implement at minimum a 90-day soft edit.
 - This is an opportunity for MCO to accomplish CLIA validation by identifying and performing outreach to providers to update PEMS with CLIA certification before a hard edit is in place.
 - MCO have the ability to implement soft editing before 03/01/2026.
 - MCO must attest by March 06, 2026, confirming soft launch editing.

- With DOS starting June 01, 2026, all MCOs are required to have hard editing in place to start denying claims if a provider bills for a procedure without appropriate CLIA certification.
 - MCO must attest by June 05, 2026, confirming hard edits in place.

Please note that March 01, 2026, and June 01, 2026, implementation dates for the soft launch and hard launch are based on claim 'DOS,' so all MCOs are aligned, and the application of the requirements does not impact any adjusted claims with DOS.

The revised deadline for when MCOs are required to start denying claims that lack the appropriate CLIA certification are based on claims with DOS starting June 01, 2026.

HHSC expects that MCO claims systems be set up to link up the type of CLIA certification and billable procedure codes to determine how the procedures will process, depending on CLIA waived status and the provider's CLIA certification type. All providers that bill laboratory services must have CLIA certification for the procedure code being billed. If a provider bills for a procedure without appropriate CLIA certification, reimbursement must be denied.

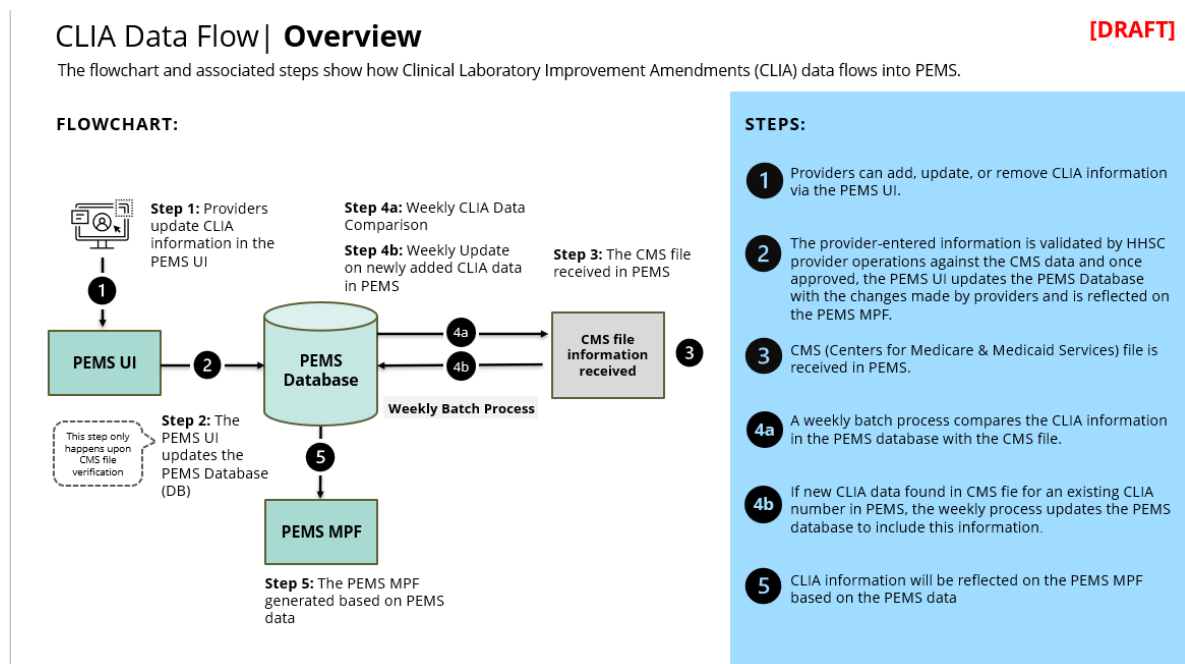
Please note that Texas Medicaid MCOs must provide all medically necessary, Medicaid-covered services to eligible clients. Administrative procedures such as prior authorization, pre-certification, referrals, and claims/encounter data filing may differ from traditional Medicaid (fee-for-service) and from MCO to MCO.

MCO Notice Date	Title
<u>November 24, 2025</u>	<u><i>Revised Implementation Timeframes of CLIA Certification Data</i></u>
October 30, 2025	<i>Delay of Implementation of CLIA Certification Data</i>
September 16, 2024	<i>Update to CLIA Certification Data within PEMS MPF</i>

April 15, 2024 *Update to CLIA Certification Data within PEMS MPF*
 November 09, 2023 *Annual HCPCS Updates to Include Laboratory Certification (LC) Codes CLIA Specialty And Subspecialty and Medicare Coverage Status Information*
 October 13, 2022 ***Informational Update/Change** CLIA Certification Required for Claims*

2. Question: How does the CLIA process begin in PEMS? What does the weekly Centers for Medicaid & Medicare Services (CMS) file update in PEMS?

Answer: Refer to the data flow diagram.



All providers can provide CLIA information in PEMS by adding the following information to each of their applicable practice locations at the program level. This information is displayed under Record ID #355 in PEMS MPF:

- Certification Number (a.k.a. CLIA ID Number)
- Certification Code = Accreditation
- Issuer Code (License Issue Code = CLIA)
- Certification Type Code/CLIA Lab Code
- Certification Effective Date
- Certification Expiration Date

Below is an excerpt from PEMS MPF JIP layout for reference.

Enrollment Practice Program Certification/Accreditation/Designation - Record ID: 355 - List of Certifications/Accreditations/Designations associated to the Enrollment Practice Program									
Enrollment Practice Program Cert/Accred/Des	1	Record ID	3	1	3	AN			
Enrollment Practice Program Cert/Accred/Des	2	National Provider Id	10	4	13	AN			
Enrollment Practice Program Cert/Accred/Des	3	Enroll Practice Program Id	36	14	49	GUID			
Enrollment Practice Program Cert/Accred/Des	4	Program Code	20	50	69	AN			
Enrollment Practice Program Cert/Accred/Des	5	Program Certification Effective Date	10	70	79	Date	CCYY-MM-DD		
Enrollment Practice Program Cert/Accred/Des	6	Program Certification Terminate Date	10	80	89	Date	CCYY-MM-DD		
Enrollment Practice Program Cert/Accred/Des	7	Certification Effective Date	10	90	109	Date	CCYY-MM-DD		
Enrollment Practice Program Cert/Accred/Des	8	Certification Expiration Date	10	110	119	Date	CCYY-MM-DD		
Enrollment Practice Program Cert/Accred/Des	9	Certification Code	20	120	139	AN			
Enrollment Practice Program Cert/Accred/Des	10	Certification Number	25	140	164	AN			
Enrollment Practice Program Cert/Accred/Des	11	Issuer Code	50	165	214	AN			
Enrollment Practice Program Cert/Accred/Des	12	Certification Type Code/CLIA Lab Code	20	215	234	AN			If Issuer Code=CLIA, this field includes Certification Type Code OR CLIA Lab Code.
Enrollment Practice Program Cert/Accred/Des	13	State Code	2	235	236	AN			

On a weekly basis, for any provider records where CLIA Number is provided and the Issuer is marked as 'CLIA', PEMS compares the CLIA Number, Certification Type Code OR CLIA Lab Code, Certification Effective Date, and Certification Expiration Date against the CMS file. If PEMS find the record in CMS with a different Effective and Expiration date, then PEMS will insert a new record under that Certification Type Code OR CLIA Lab Code in Record ID # 355 showing Certification Effective and Expiration dates from CMS file.

Data saved in PEMS from CMS File				
	Id	CLIANumber	LabCode	EffectiveDate
1	1	01D0026356	110	2000-08-21 00:00:00.000
2	2	01D0026356	120	2004-07-14 00:00:00.000
3	3	01D0026356	120	2000-08-12 00:00:00.000
4	4	01D0026356	130	2004-07-14 00:00:00.000

3. Question: When does PEMS require providers to input CLIA information? Are there any required provider types?

Answer: There is no systematic restriction within PEMS that require certain provider types when enrolling. However, the Independent Laboratory Provider Types* do require CLIA as a prerequisite for enrollment and will undergo a manual review by a TMHP provider enrollment specialist, who will ensure that CLIA information is entered if the provider type requires it. Furthermore, any provider type is permitted to submit CLIA information.

*Independent Laboratory Provider Types:

- 23 Independent Lab/Private Owned Lab (No Physician Involvement)
- 24 Independent Lab/Private Owned Lab (Physician Involvement)

4. Question: Please confirm that these requirements '*All providers that bill laboratory services must have CLIA certification for the procedure code being billed*' are applicable to all provider types and specialties that are billing laboratory service codes. For all providers, if the provider has not entered their CLIA certification into PEMS, the

MCOs are to deny the laboratory service line billed on the claim for ALL/ANY provider types and specialty billing lab codes, with no exceptions.

Answer: Yes, that is correct. Under Texas Medicaid policy, the CLIA certification requirement applies to all provider types and specialties billing laboratory procedure codes (including waived, moderate, and high complexity tests). No provider type exceptions. CLIA requirements are federally mandated and apply to any entity or individual performing and billing laboratory testing. This includes physicians, clinics, hospitals, FQHCs, RHCs, independent labs, and any other specialty submitting lab CPT/HCPCS codes.

Policy References:

- a. Texas Medicaid Provider Procedures Manual (TMPPM), Laboratory Services Handbook, Section 1: CLIA requirements for all providers performing laboratory testing.

5. Question: What is the process for providers to update/add CLIA info in PEMS?

Answer: Providers can update their CLIA certifications in the Provider Enrollment and Management System (PEMS) by creating a PEMS Maintenance License request and clicking the License/Certification/Accreditation page. CLIA certifications are practice location specific, there should be a separate CLIA number for each location, and provider must associate the CLIA certifications to their programs associated to their practice location. Note: If a provider is within their revalidation window, they will not be able to create and submit a PEMS Maintenance License request and will need to update their CLIA certification through a Revalidation request in PEMS. Once the request has been approved the CLIA updates will reflect in the PEMS MPF. Provider records that have been updated by 9 P.M. CST in PEMS will appear in the next Master Provider File (MPF) that is sent overnight.

For more information about updating CLIA certifications in PEMS, refer to www.tmhp.com/topics/provider-enrollment/pems/licenses.

Refer to question #2 for more information related to the CMS CLIA data updates in PEMS.

6. Question: Will HHSC consider incorporating the full CMS CLIA source file into PEMS so that MCOs are not denying provider claims unnecessarily?

Answer: HHSC incorporated the full CMS CLIA source file into the PEMS MPF on April 14, 2023. The weekly CMS CLIA files received are maintenance files, meaning the evolving updates will drop off. HHSC incorporates the weekly CMS file updates into the PEMS MPF. The PEMS MPF retains the full history.

7. Question: The data flow diagram (above) shows that a provider needs to enter its CLIA information in PEMS first. Otherwise, CMS file will not add any CLIA information to this provider. Is that correct?

Answer: That is correct. PEMS does not check the CMS file for any records where the provider has not added their CLIA information as stated above.

However, when the weekly CMS CLIA maintenance file comes in and includes a provider that has not yet added their CLIA information in PEMS, PEMS will store the data in staging tables. At a later time, when the provider adds the CLIA Certification information in PEMS, the system will compare the data with the staging table and update accordingly.

8. Question: Does the weekly CMS file update CLIA information in each practice location in PEMS?

Answer: Yes. The weekly CMS file updates CLIA information in each practice location in PEMS, if the provider has associated the CLIA information with the respective practice location for a program (to be reflected on 355 record). Refer to the process described above.

9. Question: Does the weekly CMS file inserts NEW certification (certifications type code/CLIA lab codes) in PEMS?

Answer: If a CLIA ID number exists in PEMS with an Issuer Code of 'CLIA' and there are new Certifications Type code/CLIA lab codes in the CMS file, PEMS will insert new certification(s).

If the CLIA ID number is not found in PEMS, the process does not insert new certification codes in PEMS.

10. Question: CLIA information is found in PEMS MPF Record ID #s 060 and 355? What is the difference between the two? What is the source of data in each Record ID? Which Record should MCOs use for CLIA?

Answer: **Record ID 060** contains a list of certifications, accreditations, and designations associated with the *Enrollment National Provider Identifier (NPI)* at the Enrollment level as entered by the provider in PEMS. This record does

get updated from CMS file for 'Certification Expiration Date'. However, this record does not contain Certification Type Code/CLIA Lab Code details.

Record ID 355 contains a list of certifications, accreditations, and designations associated with the *Enrollment Practice Program* at the 300 level (program practice) and is also entered by the provider. Once the provider associate/assign their CLIA certification at program practice level, CLIA data will then reside in Record ID 355 instead of 060.

MCOs should use Record ID # 355 for CLIA as it contains data at the program practice level. CLIA is a location specific certification. In PEMS, providers have to associate the appropriate CLIA certification to the applicable location under the relevant program (such as Acute Care-Fee-for-Service (FFS) and Children with Special Health Care Needs (CSHCN)), which will reflect on Record 355 of the PEMS MPF. For a given NPI and CLIA number, the CLIA data should be consistent across the associated Enrollment Practice Program Association ID (EPPIDs).

11. Question: HHSC has confirmed that PEMS does not add CLIA certification data from the CMS file unless the provider has already entered their CLIA information into PEMS. On April 14, 2023, HHSC incorporated the full CMS CLIA source file into the PEMS master provider file for providers who had their CLIA certification numbers entered in PEMS at that time. Since then, HHSC has been incorporating ongoing weekly CMS CLIA maintenance files into the PEMS master provider file; however, these files only update existing CLIA records and do not add CLIA certification for providers without a matching CLIA ID already in PEMS. If a CLIA ID number exists in PEMS with an issuer code of "CLIA" and there are new certification type codes in the CMS file, PEMS will insert the new certification. If the CLIA ID number is not found in PEMS, the process does not insert new certification codes. Given this, should MCOs deny laboratory service claims for any provider type or specialty when the provider's CLIA certification is not entered into PEMS, even if the CLIA certification appears in the CMS file or in the MCO's internal records? Additionally, would such a claim be considered an unclean claim, and would interest apply if the provider later enters the CLIA certification into PEMS and requests claim adjustment for payment?

Answer: Yes. HHSC requires that all provider types and specialties billing laboratory services must have their CLIA certification information recorded in PEMS before MCOs may process and pay claims for those services. MCOs

must deny claims for laboratory services if the CLIA certification is not in PEMS, regardless of whether it appears in the CMS file or in the MCO's internal system. HHSC policy relies on PEMS as the authoritative source for CLIA certification verification for claims adjudication.

A clean claim per the Uniform Managed Care Contract (UMCM) "A Clean Claim" is submission with all required data allowing the MCO to adjudicate and accurately report it. A claim submitted without CLIA certification is considered not a clean claim because it lacks critical data element in PEMS required for accurate adjudication. If a claim denied for missing CLIA information was not a clean claim at the time of submission, HHSC would not expect interest to accrue during that period. Interest is only owed on clean claims that were not paid within the contractual deadline of 10 or 30 days. Once the provider enters the CLIA certification into PEMS, the claim becomes a clean claim at that point; if the provider requests the MCO to adjust or resubmit and the MCO fails to pay within the required contract timeframe, interest may then apply from the clean-claim date forward.

Policy References:

- a. Texas Medicaid Provider Procedures Manual (TMPPM), Laboratory Services Handbook, Section 1: CLIA requirements for all providers performing laboratory testing.
- b. Uniform Managed Care Manual (UMCM) §8.1.4.3: MCO responsibility to verify provider enrollment and certification requirements in PEMS for payment.
- c. 42 CFR §493: Federal CLIA regulations applying to all entities performing laboratory testing.

12. Question: At the time of CLIA implementation by HHSC, were the providers communicated that they can add/update/insert CLIA data in PEMS? What channels were used for communication?

Answer: Yes, communication was provided when CLIA 355 field was added to the PEMS MPF. Provider notifications were posted on TMHP.com during the following timeframes:

- a. 10/26/2022 - CLIA Certification Required for Claims <https://www.tmhp.com/news/2022-10-26-clia-certification-required-claims>

- b. 02/23/2023 - Reminder: CLIA Certification Required for Claims
<https://www.tmhp.com/news/2023-02-03-reminder-clia-certification-required-claims>
- c. 03/03/2023 - Reminder: CLIA Certification Required for Claims
<https://www.tmhp.com/news/2023-02-03-reminder-clia-certification-required-claims>
- d. 04/07/2023 - Reminder: CLIA Certification Required for Claims
<https://www.tmhp.com/news/2023-04-07-reminder-clia-certification-required-claims>

Additionally, HHSC sent out a recent reminder provider notification on TMHP.com and through the GovDelivery notification process:

- e. 07/31/2025 – CLIA Certification Required for Laboratory Service Claim
<https://www.tmhp.com/news/2025-07-31-clia-certification-required-laboratory-service-claims>
- f. 08/05/2025 - CLIA Certification Reminders [GovDelivery notification]

13. Question: Is there a PEMS MPF hierarchical data structure that MCOs need to consider when validating CLIA certificates?

Answer: MCOs should consider the following hierarchical data in PEMS MPF when validating CLIA certificates:

- 1. Enroll Practices (Record 200)
 - The provider must have an active Enroll Practice record.
- 2. Enroll Practice Programs (Record 300)
 - The provider must have an active Enroll Practice Program record.
- 3. Enroll Practice Program Disenrollment/Deactivation (Record 330)
 - Consider Active PDC codes disenrolled of the program except for codes 46, 60, 63, and 67.
- 4. Enrollment Practice Program Certification (Record 355)
 - Consider the Certification Effective Date and Certification Expiration Date to determine if the certification is active for the applicable CLIA Number and Certification Type code/CLIA Lab code.

14. Question: Are there any validations on CLIA in the MCO encounter processing solution?

Answer: Following HIPPA edit exists in the MCO encounter processing for CLIA data. There are no Business edits.

- HIPPA Edit - 0x3939381 (F)- Value of element REF02 (CLIA Number) is incorrect. Expected value is CLIA number (format is '10 characters where the third character is 'D').

15. Question: Does the NPI have to be active along with the CLIA Cert ID to be considered for CLIA?

Answer: Yes, the NPI must be active for a CLIA ID. The CLIA Program requires that a unique CLIA ID and servicing location information be provided for every location where testing is performed. Additionally, any facility that performs laboratory tests is required by federal law to have a CLIA certificate, which includes the NPI.

16. Question: Where can a provider reference the policy for enrolling in CLIA?

Answer: Providers can reference the Texas Medicaid Providers Manual (TMPPM) at www.TMHP.com. This can be found under the Radiology and Laboratory Services Handbook: 2.1.1 Clinical Laboratory Improvement Amendments (CLIA) and 2.1.2 CLIA Requirements.

17. Question: Is there a specific certification that requires providers to submit the QW?

Answer: Yes, there is a specific certification that requires providers to submit the QW modifier. If a lab has a Certificate of Waiver or a Certificate of PPMP, then the QW modifier is mandatory for procedures included on the CMS waived list. Providers with certain certification types must add the QW modifier to the procedure code for all applicable CLIA waived or PPM tests they submit for reimbursement. The QW modifier indicates that the diagnostic lab service is a CLIA waived test, and the provider must hold at least a Certificate of Waiver to legally perform clinical laboratory testing. This certification ensures compliance with the requirements for submitting waived tests.

18. Question: Can any provider use the QW modifier, or is it restricted to certain certifications?

Answer: The QW modifier is not restricted to any single provider or certification. It is used by any provider who has a CLIA certificate of waiver to indicate that a test is performed at a waived complexity level. This modifier is mandatory for procedures included on the Centers for CMS' waived list, with a few exceptions. However, if a lab has a CLIA certification of compliance, the QW modifier is not required. The certificate of compliance allows labs to perform moderately and/or high complex tests, while the

certificate of waiver is specifically for CLIA-waived tests. It is essential for providers to verify the type of CLIA certification their lab holds and to use the appropriate modifier accordingly to ensure proper claims payment and avoid denials.

19. Question: If a provider submits the QW without needing it, are the claim lines still payable?

Answer: If a provider submits the QW modifier without needing it, the claim lines may still be payable.

Additional information that may be helpful clarification:

- a. The QW modifier indicates that a test is CLIA-waived or has a CLIA Certificate of Waiver. A CLIA waiver allows facilities to perform laboratory tests categorized as “waived complexity” under CLIA rules. Some CLIA-waived tests have unique Healthcare Common Procedure Coding System (HCPCS) procedure codes, and some must have a QW modifier included with the HCPCS code. CMS provides an updated list of waived tests to Medicare contractors on a quarterly basis, which may be found here: [Waived Tests | Laboratory Quality | CDC](#). Depending on the codes submitted, they may still be payable without the modifier, depending on the provider’s CLIA certification type. Providers who have a **Full/Accredited Certification** may bill any CLIA procedure codes, regardless of modifiers that may be required for other certification types.
- b. There are also CLIA certificates for provider-performed microscopy (PPM) procedures, which permit physicians and midlevel practitioners to perform a limited list of moderate complexity microscopic tests, as well as waived tests, as part of a patient’s visit.
- c. HHSC expects that MCO claims systems be set up to link up the type of CLIA certification and billable procedure codes to determine how the procedures will process, depending on CLIA waived status and the provider’s CLIA certification type.

Type of CLIA Certification	Billable Procedure Codes
Full/Accredited Certification	May bill any laboratory procedure, regardless of modifier that is required for other certification types
Waived Certification	May only bill CLIA-waived procedures (e.g., codes that do not require the QW modifier to be designated as CLIA waived tests, and procedures with the QW modifier)
PPMP (Partial) Certification	May only bill for Provider-Performed Microscopy Procedures, CLIA-waived procedures (e.g., codes that do

Type of CLIA Certification	Billable Procedure Codes
	not require the QW modifier to be designated as CLIA waived tests, and procedures with the QW modifier)
No CLIA Certification on file	May only bill procedures for which a CLIA certificate is not required

- d. The laboratory is not required to declare specialties or sub-specialties on these types of certificates.
 - CLIA Certificates of Waiver
 - Provider Performed Microscopy Procedures (PPMP)
 - Certificate of Registration (Precursor to Compliance or Accreditation)
- e. Only labs that have been found in compliance by a certification survey, either by Texas HHSC (Certificate of Compliance) or an equivalent accrediting body (Certificate of Accreditation) will display the LC codes, and only for non-waived testing.
- f. Please refer to the CLIA references materials below for more information:
 - MLN Matters publication by CMS on updates to CLIA Waived procedures: <https://www.cms.gov/files/document/mm12581-new-waived-tests.pdf>
 - List of CLIA Waived procedures from CDC: <https://www.cdc.gov/clia/docs/tests-granted-waived-status-under-clia.pdf>
 - CMS list of provider-performed microscopy procedures: <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/ppmplist.pdf>

20. Question: If a provider is only billing CLIA waived lab services, is the MCO expected to deny those services if properly billed with the QW modifier, but the provider has not entered their CLIA waived certification in PEMS?

Answer: Yes, if the provider hasn't entered their CLIA waiver information into PEMS, the MCO would generally be expected to deny those services even if they are billed with the modifier because QW tells the payer the test was performed under a CLIA-waived certificate. Without a matching waiver on file, the claim cannot be validated against federal and state requirements. PEMS requirement for Texas Medicaid and most MCOs pull provider CLIA information from PEMS for claims adjudication. If the certification is not in PEMS, the system treats the provider as not authorized

to perform CLIA waived testing, so the claim will deny for "missing or invalid CLIA certification." The MCO expectation is that MCOs are contractually required to follow Medicaid's provider enrollment and certification verification rules. The denial would be correct until the provider updates their CLIA waiver in PEMS. Once the CLIA waiver is added in PEMS and effective for the date of service, claims can be reprocessed.

21. Question: Are MCOs required to deny claims billed with lab services if the MCO has the provider's CLIA certification information in the MCO system, but that information is not entered into PEMS by the provider?

Answer: If the CLIA certification is not recorded in PEMS, the claim is to be denied even if the provider gave the CLIA number directly to the MCO. MCOs must follow TMHP's enrollment data for claims adjudication. Internal MCO records cannot substitute for missing PEMS data.

22. Question: What are the Laboratory Certification (LC) CLIA Specialty and Subspecialty Codes?

Answer: The full list of CLIA certification specialty type codes from CMS can be found in the following link: <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/lccodes.pdf>

**LABORATORY CERTIFICATION (LC) CODES
CLIA SPECIALTY AND SUBSPECIALTY INFORMATION**

LC Code	Specialty - Subspecialty
010	Histocompatibility
110	Microbiology - Bacteriology
115	Microbiology - Mycobacteriology
120	Microbiology - Mycology
130	Microbiology - Parasitology
140	Microbiology - Virology
210	Diagnostic Immunology - Syphilis Serology
220	Diagnostic Immunology - General Immunology
310	Chemistry - Routine Chemistry
320	Chemistry - Urinalysis
330	Chemistry - Endocrinology
340	Chemistry - Toxicology
400	Hematology
510	Immunohematology - ABO Group & Rh type
520	Immunohematology - Antibody Detection (transfusion)
530	Immunohematology - Antibody Detection (non-transfusion)
540	Immunohematology - Antibody Identification
550	Immunohematology - Compatibility Testing
610	Pathology - Histopathology
620	Pathology - Oral Pathology
630	Pathology - Cytology
800	Radiobiassay
900	Clinical Cytogenetics

23. Question: Is HHSC providing a full file of the CLIA data from the HCPCS file to MCOs?

Answer: HHSC is providing a full file going back to January 01, 2020. This includes information pulled from the CMS HCPCS files and the CLIA workaround files. Please note these files are confidential for internal use only.

- **Zipfolder:** *Confidential for Internal Use only_CLIA HCPCS Data*
 - This document will be uploaded on August 21, 2025, to MCOHub for your retrieval and is posted in the following folder path in MCOHub – COMMON > GENERAL > MCO.
 - In accordance with HHS SFTP, data files must not be stored on SFTP servers for longer than 15 calendar days. All files must be routinely downloaded and stored to a permanent location prior to the 15-day purge.
- **Lab Certifications Document:**
 - Covers data from January 2020 to July 2025.
 - First Tab:
 - Contains a combined list of all lab certifications from 01/01/2020 to 07/01/2025.
 - Blue Highlighted Codes: These procedure codes have been discontinued.
 - Pink Highlighted Codes: These codes had a description change, but the lab certifications stayed the same.
 - A legend explaining the highlights is included at the top right of the spreadsheet.
 - Remaining Tabs:
 - These are from the CMS HCPCS files for each quarter.
- **CLIA Workaround Spreadsheet Document:**
 - Covers data starting from July 1, 2024.
 - This is when HHSC began compiling information for a workaround, since HHSC was no longer receiving updated Laboratory Certification (LC) edits for HCPCS codes from CMS in the annual and quarterly HCPCS files. Similar to other States, Texas Medicaid has created a workaround process for FFS claims processing to review new and revised codes found in the annual and quarterly HCPCS files to identify a similar lab procedure that does have a certification code and apply that same certification code to the new or revised HCPCS code. HHSC will share FFS certification code recommendations with the MCOs for use, or MCOs may develop their own certification code determination process.
 - Each Tab:
 - Represents a separate quarter.

24. Question: As per the guidelines, we are expected to match at the program practice level 355, ensuring that each location has a unique CLIA ID and accurate servicing location information.

Are we required to enforce an exact match for the servicing address? For example, if a Provider's CLIA certification address has "Street" in full while their claim is submitted using the abbreviation "ST." should we deny claims based on this discrepancy? Additionally, are there any other address match criteria we should adhere to for proper CLIA claim adjudication and alignment across all MCO's?

Answer: Yes, abbreviations are acceptable and compliant with HHSC Medicaid.

25. Question: Please confirm the crosswalk of CLIA certificates based on the certification type codes included in the PEMS file layout. Please find our interpretation of the crosswalk detailed below and advise which certification type codes map to the CLIA certificates to confirm accuracy. Included is the PEMS file layout for reference.

PEMS Certification Crosswalk	Types of CLIA Certificates
2	Certificate of Waiver - This certificate is issued to a laboratory to perform only waived tests
4	Certificate for Provider-Performed Microscopy Procedures (PPMP) - This certificate is issued to a laboratory in which a physician, midlevel practitioner or dentist performs no tests other than the microscopy procedures. This certificate permits the laboratory to also perform waived tests
9	Certificate of Registration (COR) - This certificate is issued to a laboratory that enables the entity to conduct moderate or high complexity laboratory testing or both until the entity is determined by survey to be in compliance with the CLIA regulations.
1	Certificate of Compliance (COC) - This certificate is issued to a laboratory after an inspection that finds the laboratory to be in compliance with all applicable CLIA requirements.
3	Certificate of Accreditation (COA) - This is a certificate that is issued to a laboratory on the basis of the laboratory's accreditation by an accreditation organization approved by CMS.

PEMS File Layout:

CertificationType Code	1	Regular
CertificationType Code	2	Waiver
CertificationType Code	3	Accreditation
CertificationType Code	4	Provider-Performed Microscopy Procedure (PPMP)
CertificationType Code	5	Partial Accredited
CertificationType Code	9	Registration

Answer: The current CLIA Certification Types published by CMS ([TYPES OF CLIA CERTIFICATES](#)) are listed below and we have provided the crosswalk:

- 1 - Regular (Certificate of Compliance (COC)) This certificate is issued to a laboratory after an inspection that finds the laboratory to be in compliance with all applicable CLIA requirements.
- 2 – Waiver (Certificate of Waiver) This certificate is issued to a laboratory to perform only waived tests.
- 3 – Accreditation (Certificate of Accreditation (COA)) This is a certificate that is issued to a laboratory on the basis of the laboratory's accreditation by an accreditation organization approved by CMS.
- 4 - Provider-Performed Microscopy Procedure (PPMP) This certificate is issued to a laboratory in which a physician, midlevel practitioner, or dentist performs no tests other than microscopy procedures. This certificate also permits the laboratory to perform waived tests.
- 9 – Registration (Certificate of Registration (COR)) This certificate is issued to a laboratory that enables the entity to conduct moderate- or high-complexity laboratory testing or both until the entity is determined by survey to be in compliance with the CLIA regulations.
- HHSC expects that MCO claims systems be set up to link up the type of CLIA certification and billable procedure codes to determine how the procedures will process, depending on CLIA waived status and the provider's CLIA certification type.

26. Question: Confirm whether HHSC maintains or publishes a comprehensive list of billable CPT/HCPCS codes that are allowable under CLIA (including for waived, PPM/PPMP, and other CLIA certificates). If such a list exists, would you please point me to where I can access it (e.g. in a policy handbook, on the HHSC website, or via a downloadable document)? If not, do you know the best reference resource(s) that HHSC or CMS relies upon for determining which laboratory codes are covered under CLIA?

Answer: HHSC submitted MCO notices and provided the full CLIA HCPCS list on August 21, 2025, and an updated version on October 16, 2025, via MCOHub in the following folder location Common > General > MCO. In the past, these MCO notifications (labeled: *LC Codes CLIA Specialty And Subspecialty Coverage Status Information*) have been sent out on a quarterly basis. HHSC will be providing an updated comprehensive list of CLIA CPT/HCPCS codes moving forward on a quarterly basis.

HHSC utilizes the CMS HCPCS files to identify new, revised, or discontinued laboratory codes, and the CMS Medicare Learning Network (MLN) Connects newsletter publications to help determine which laboratory codes are covered under CLIA.

27. Question: Do the LABCERT column headers found in the CLIA CPT/HCPCS file reflect the CLIA Certification type codes (1 (Regular), 2 (Waiver), 3 (Accreditation), 4 (PPMP), 9 (Registration))?

Procedure Code	LONG DESCRIPTION	LABCERT1	LABCERT2	LABCERT3	LABCERT4	LABCERT5
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Answer: No, the LABCERT column headers are not reflective of the CLIA Certification type codes. The column headers are an arbitrary naming convention pulled from the CMS HCPCS file to list out the 3-digit lab specialty/sub-specialty codes that are tied to a HCPCS code.

28. Question: What is the date to start denying claims? When changes become effective it can be Date of Service (DOS) driven, i.e., any claim with a DOS 06/01/2026 forward would be impacted OR it can be receipt date driven, i.e., anything received regardless of DOS would be subject to the rule, i.e., claim DOS was 03/15/2026, but because it was not received until 06/01/2026 it would be subject to the new rules. This is why we're asking for clarification because we can make it either but wanted to minimize any impact for provider complaints.

Please advise was HHSC's intent to be 06/01/2026 claim DOS or any claims received 06/01/2026 or later would be subject to the CLIA requirements? CLIA requirements for traditional Medicaid have been enforced for more than 25 years for Traditional Medicaid thus the questions on effective dates for the MCO enforcement.

Answer: The revised effective date for when MCOs are required to start denying claims that lack the appropriate CLIA certification are based on claims with dates of service starting June 01, 2026.

29. Question: We found HCPCS codes on the CMS list that are not the State list for CLIA. Could you please provide clarification on how we should handle those codes?

Answer: You can refer these types of questions to the MedicaidBenefitRequest@hhsc.state.tx.us mailbox. Please provide which codes you are referring to and provide additional clarification on what CMS list you are comparing it to, so that HHSC can analyze it further to see if additional codes should be added to the list.

30. Question: Does PEMS verify the practice location address against the address listed on a provider's CLIA certification during enrollment or revalidation. As you know, for billing purposes, it is critical that the address associated with the CLIA certification matches the provider's practice location.

Answer: Per current PEMS system logic, there is no automated verification between the practice location address and the address listed on a provider's CLIA certification during enrollment or revalidation. However, within the TMHP Provider Enrollment process, there is a manual validation step to confirm that the address on the CLIA certificate matches the PEMS practice location. Note that the suite number is not required to match.

31. Question: We previously requested assistance from the PEMS+ team, who advised that the provider has not associated a license of type=CLIA to this EPID location, and to fix the issue, the provider must create a maintenance license request to update the info in PEMS UI.

We contacted the provider to communicate the above guidance; however, the provider has responded that they cannot update the CLIA data in PEMS because the certification is not set to expire until February 2026, and that PEMS only allows updates to CLIA data to be made within three months of the certification expiration date.

Is the provider correct in their understanding that they are unable to create a maintenance license request at this time (as it is not close enough to the CLIA expiration date), or is a maintenance license request allowed regardless of the future CLIA certification expiration date?

Answer: PEMS currently does not have system restrictions that prevents a provider from updating their CLIA certification, even if the certification date is in the future. Providers should be able to log in to PEMS and update their certification as needed. If a provider experiences issues updating their CLIA certification in PEMS, they should contact the TMHP Provider Enrollment line at 1-800-925-9126, Option 3. This contact information is also available on the TMHP Contact page.

32. Question: Please confirm it is HHSC's expectation that all MCOs deny a provider's lab claims subject to CLIA requirements received for processing as of 06/01/26, if the provider's CLIA certification for the billed claim exists, but is not present in PEMS.

Answer: It is a provider's responsibility to verify that the CLIA information in PEMS is correct and accurate. All providers that bill laboratory services must have CLIA certification for the procedure code being billed. If a provider bills for a procedure without appropriate CLIA certification, reimbursement must be denied. Please refer to the latest provider notification posted to TMHP.com: [CLIA Certification Required for Laboratory Service Claims | TMHP](#) and question # 28.

33. Question: Please confirm that HHSC requirement to deny claims billed with CLIA-applicable lab codes in which the CLIA certification is not present in PEMS is applicable to all provider types/specialties, including hospitals, non-hospital facilities, practitioners, clinics, and labs.

Answer: Yes, claims should be denied if a CLIA certification is not present. Even in cases where a test is CLIA waived, a provider would be expected to have a Certificate of Waiver or a Certificate of PPMP, then the QW modifier is mandatory for procedures included on the CMS waived list. Providers with certain certification types must add the QW modifier to the procedure code for all applicable CLIA waived or PPMP tests they submit for reimbursement.

34. Question: If a provider maintains CLIA certification for a billed claim, but the applicable certification is not present in PEMS as of 06/01/26:

a. Is the provider able to add CLIA certification information in PEMS, and will that entry into PEMS be applicable to prospective claims only, or also applicable to claims prior denied for no CLIA Certification in PEMS?

Answer: The revised effective date for when MCOs are required to start denying claims that lack the appropriate CLIA certification are based on claims with dates of service starting June 01, 2026. If a provider went into PEMS on June 01, 2026, to add a CLIA certification effective date April 01, 2026, they would be able to do so, assuming

that they are within their license period. Once the CLIA certificate is added in PEMS and effective for the date of service, claims can be reprocessed.

b. If the provider adds applicable CLIA certification information into PEMS 06/01/26 or after:

i. Is the provider eligible to appeal claims prior denied for lack of CLIA certification in PEMS as of 06/01/26?

Answer: Yes, if a provider updates their CLIA certification within PEMS, they are eligible to appeal claims after a denial.

ii. Are the MCOs responsible for identifying CLIA certification entries into PEMS post 06/01/26 and reprocessing any claims denied for lack of CLIA certification without provider appeal?

Answer: It would be up to the provider to appeal assuming that their CLIA certification is within their license period and MCOs would then be required to reprocess claims.

35. Question: How do MCOs identify providers who are missing CLIA certification?

Answer: HHSC will be providing an updated comprehensive list of CLIA CPT/HCPCS codes moving forward on a quarterly basis via MCOHub. MCO can use the comprehensive CLIA CPT/HCPCS list, to identify providers who bill those procedure codes and compare it to providers who have CLIA certification on PEMS MPF. If the provider is billing CLIA procedure codes and does not show a CLIA certification on the PEMS MPF, outreach to the provider will be needed. MCOs should conduct outreach to providers, to direct them to add CLIA certification number to PEMS.

36. Question: We have been reviewing the comprehensive list of HCPCS codes related to CLIA certificates and would appreciate clarification regarding the LABCERT columns in the spreadsheet provided. Specifically, we are seeking to confirm whether the following LABCERT labels correspond to CLIA certificate types as defined by CMS or PEMS:

- **LABCERT 1 = PEMS (Regular) or CMS (Certificate of Waiver)**
- **LABCERT 2 = PEMS (Waiver) or CMS (PPMP)**
- **LABCERT 3 = PEMS (Accreditation) or CMS (Registration)**
- **LABCERT 4 = PEMS (PPMP) or CMS (Certificate of Compliance)**

- **LABCERT 5 = PEMS (Partial Accredited) or CMS (Accreditation)**

Answer: The correct crosswalk for the CLIA Certification Types are the following:

- 1 - Regular (Certificate of Compliance (COC)
- 2 - Waiver (Certificate of Waiver)
- 3 - Accreditation (Certificate of Accreditation (COA)
- 4 - Provider-Performed Microscopy Procedure (PPMP)
- 9 - Registration (Certificate of Registration (COR)

Refer to question #27 - Answer: No, the LABCERT column headers are not reflective of the CLIA Certification type codes. The column headers are an arbitrary naming convention pulled from the CMS HCPCS file to list out the 3-digit lab specialty/sub-specialty codes that are tied to a HCPCS code.

37. Question: For practice sites there can be multiple programs, not all of which the MCOs are allowed to participate in. If the provider puts the CLIA on a program such as CHSCN which is not an MCO program, can the MCO use that for TMP program at the same location?

Same 200 level, different 300 program.

Answer: CLIA matches the practice location that can perform laboratory services. The program (example CSHCN or Medicaid) is irrelevant for CLIA. The provider could have Medicaid clients, CSHCN clients, and 3rd party insurance clients and get paid from all those programs using the same CLIA.

38. Question: How soon will MCOs receive the records after a provider updates them?

Answer: This depends on when the provider has submitted the CLIA information in PEMS and the request has been approved in PEMS. Provider records that have been updated by 9 P.M. CST in PEMS will appear in the next Master Provider File (MPF) that is sent overnight.

39. Question: If a Provider is revalidating, how can they update their CLIA information?

Answer: Providers can submit a maintenance request to update CLIA information if they are in their revalidation window as long as they have not initiated a revalidation request. Please refer to the following notification posted to TMHP.com: [Updates to PEMS Effective February 21, 2025 | TMHP](#)

If a provider has submitted their revalidation request and status is 'in progress' and has not been approved yet, the provider must include the updated CLIA information as part of their "Revalidation request" on the License/Certification/Accreditation page. Once the revalidation request has been approved, the CLIA updates will reflect in the PEMS MPF. Provider records that have been updated by 9 P.M. CST in PEMS will appear in the next Master Provider File (MPF) that is sent overnight.

For more information about updating CLIA certifications in PEMS, refer to www.tmhp.com/topics/provider-enrollment/pems/licenses.

Refer to question #2 for more information related to the CMS CLIA data updates in PEMS and question #5 that describes the process for a provider to add/update their CLIA certification.

40. Question: Is there appropriate editing on CLIA for claim adjustment reason codes (CARC) and/or remittance advice remark codes (RARC)?

Answer: MCOs may choose to use CARC (Claim Adjustment Reason Codes) and RARC (Remittance Advice Remark Codes) as they deem appropriate for CLIA processing.

41. Question: What are the expectations for denied claims for CLIA information not in PEMS?

Answer: MCOs that have already implemented CLIA editing, can continue processing as normal as long as the MCO is also editing based on PEMS data in accordance with the two-phase implementation plan.

42. Question: HHSC's proposed implementation of CLIA "warning" messaging, where claims will receive an informational message indicating that they may be denied in the future if the appropriate CLIA certification is not on file—and with this warning period running for 90 days:

- How will this apply to newly added suppliers/providers?
 - Answer: All providers (regardless if they are newly added suppliers/providers) between March 1, 2026 through May 31, 2026 should receive a warning message, informing the providers that they need to update CLIA certification information.
- Will newly enrolled suppliers/providers also receive the same 90-day ramp-up period to submit their CLIA certifications?
 - Answer: No, the 90 day soft edit period is a fixed time period across all MCOs and is not differentiated if they are a new or existing provider.

- Or will their claims pay or deny based solely on the certifications on file beginning on Day 1?
 - Answer: All MCO claims systems should start to start deny claims if a provider bills for a procedure without appropriate CLIA certification based on CLIA data provided in the PEMS MPF on June 1, 2026.

Document History

Date	Version #	Change
07/03/2025	0.1	Initial draft
07/10/2025	0.2	Updated draft for questions #1-3.
07/25/2025	0.3	Updated draft for additional questions, # 3, 4, 14, 18
08/14/2025	0.4	Updated draft for additional questions, #4, 11, 12, 20, 21
11/24/2025	0.5	Added clarification to question #5, #7, and #8. Updated draft for additional questions, #24 – 40. Updated implementation date timelines throughout FAQ.
12/22/2025	0.6	Added additional questions, #40 - 42.