Clinical Laboratory Improvement Amendment (CLIA)

Version 0.4

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 contain essential information, including laboratory certification codes (CLIA Specialty and Subspecialty). As stated in previous MCO Notices below, the MCOs have until November 01, 2025, to complete any necessary changes to their claims systems to accommodate the CLIA information.

   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.

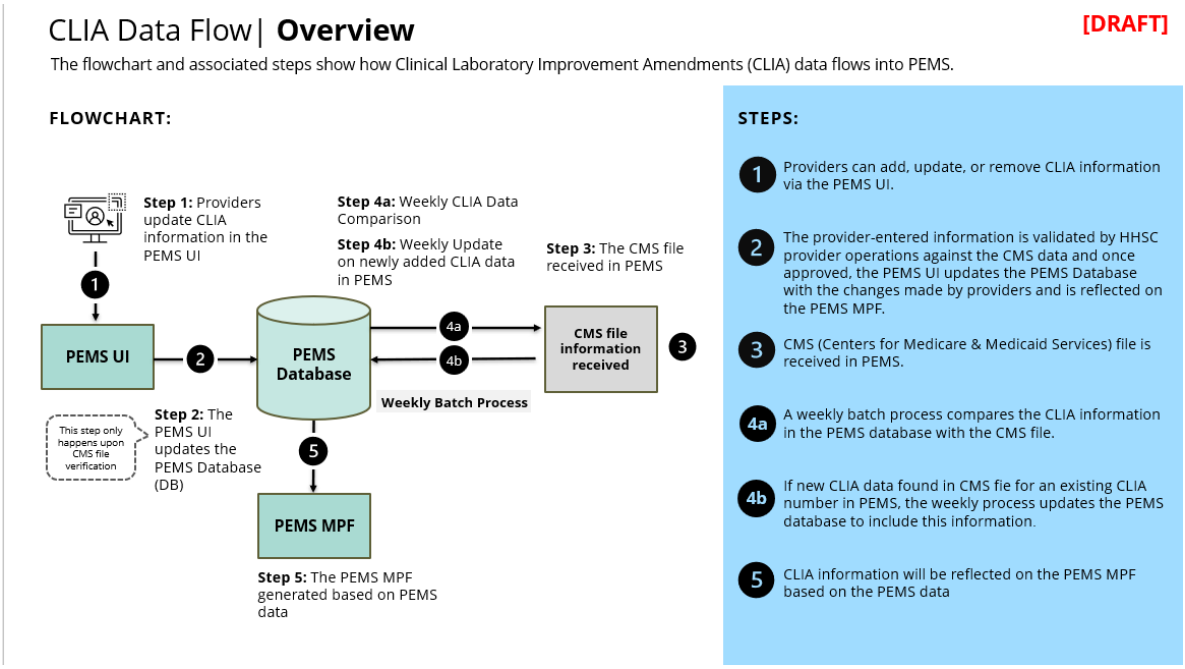
   Please note that Texas Medicaid managed care organizations (MCOs) must provide all medically necessary, Medicaid-covered services to eligible clients. Administrative procedures such as prior authorization, pre-certification, referrals, and claims/encounter data filing may differ from traditional Medicaid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

MCO Notice Date	Title
September 16, 2024	*Update to CLIA Certification Data within PEMS MPF*
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 following information to each of their applicable practice locations at the program level. This information is displayed under Record ID #355 in PEMS MPF:

a. Certification Number (a.k.a. CLIA ID Number)
b. Certification Code = Accreditation
c. Issuer Code (License Issue Code = CLIA)
d. Certification Type Code OR CLIA Lab Code
e. Certification Effective Date
f. 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		
Enrollm	4	Program Code	20	50	69	AN		
Enrollm	5	Program Certification Effective Date	10	70	79	Date	CCYY-MM-DD	
Enrollm	6	Program Certification Terminate Date	10	80	89	Date	CCYY-MM-DD	
Enrollment Practice Program	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		

CLIA Data

On a weekly basis, for any provider records where CLIA Number is provided and the Issuer is marked as 'CLIA', PEMS compare 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	EndDate
1	01D0026356	110	2000-08-21 00:00:00.000	2027-08-08 00:00:00.000
2	01D0026356	120	2004-07-14 00:00:00.000	2027-08-08 00:00:00.000
3	01D0026356	120	2000-08-12 00:00:00.000	2002-08-13 00:00:00.000
4	01D0026356	130	2004-07-14 00:00:00.000	2027-08-08 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 requires 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 PE Reviewer, 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/Privately Owned Lab (No Physician Involvement)
   - 24 Independent Lab/Privately 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 must update their CLIA certifications during their provider enrollment revalidation in the Provider Enrollment and Management System (PEMS) by clicking the License/Certification/Accreditation tab.

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

6. **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 info in PEMS first. Otherwise, CMS file will not add any CLIA info 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.

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

Answer: Yes. The weekly CMS file update CLIA information in each practice location in PEMS. 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 60 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 Electronic Positive Patient Identification (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 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 the 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 include 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 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. 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

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.

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