KERN HEALTH SYSTEMS

KERN HEALTH SYSTEMS POLICY AND PROCEDURES					
SUBJECT: Clinical Laboratory Improvements Amendments (CLIA) Certification Requirements				POLICY #: 4.47-P	
DEPARTMENT: Provider Network Management					
Effective Date: 02/2002	Review/Revised Date: 05/20/2020	DMHC		PAC	
		DHCS		QI/UM COMMITTEE	
		BOD		FINANCE COMMITTEE	

_____ Date _____
Douglas A. Hayward
Chief Executive Officer

_____ Date _____
Chief Medical Officer

_____ Date _____
Chief Operating Officer

_____ Date _____
Chief Network Administration Officer

_____ Date _____
Chief Health Services Officer

POLICY[1]:

All Kern Health Systems (KHS) laboratory contracts require compliance with 42 United States Code 263a, 42 CFR, Part 493, and Chapter 3 (commencing with Section 1200) of Division 2 of the California Business and Professions Code. KHS contracted laboratories from which members receive services are (CLIA) certified.

PROCEDURES:

1.0 PROVIDERS REQUIRED TO BE CLIA CERTIFIED

All contracted providers must have appropriate, current, unrevoked and/or unsuspended CLIA certification for each site location where testing is performed for KHS members, unless the laboratory qualifies for one of the exceptions under the CLIA Regulations. The CLIA regulations established quality standards for laboratory testing to be performed on specimens

from humans, such as blood, body fluid, and tissue, for the purpose of a diagnosis, prevention, or treatment of disease, or assessment of health. All Clinical Laboratories must be certified to perform testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 [2].

2.0 TYPES OF CLIA CERTIFICATION AND ALLOWED PROCEDURES

The following types of CLIA certification are available:

A. **Certificate of Waiver** –Issued to a laboratory that performs waived tests.

B. **Certificate for Provider-Performed Microscopy (PPM) Procedures** – allows a physician, midlevel practitioner, or dentist to perform PPM procedures during the course of a patient's visit and waived tests.

C. **Certificate of Registration** - allows a laboratory to conduct non-waived moderate and/or high complexity laboratory testing until the entity is determined by survey to be in compliance with the CLIA regulations. Only laboratories applying for a certificate of compliance or a certificate of accreditation will receive a certificate of registration.

D. **Certificate of Compliance** - issued to a laboratory after an inspection once the State Agency or CMS Surveyors find the laboratory to be in compliance with all applicable CLIA requirements. Allows a laboratory to conduct non-waived moderate and/or high complexity testing.

E. **Certificate of Accreditation** - issued to a laboratory on the basis of the laboratory's accreditation by an accreditation organization approved by Centers of Medicare and Medicaid services (CMS). Allows a laboratory to conduct non-waived moderate and/or high complexity testing.

E.1 – The following seven CMS-approved accreditations organizations are recognized by CMS:

- AABB Accreditation Program
- American Association for Laboratory Accreditation
- Accreditation Association for Hospitals and Health Systems/Healthcare facilities Accreditation Program (AAHHS/HFAP)
- American Society for Histocompatibility and Immunogenetics (ASHI)
- COLA, Inc
- College of American Pathologists (CAP)
- The Joint Commission

2.1 Procedures Subject to CLIA

The law requires that all laboratories performing testing must have a CLIA certificate for each location where testing is performed unless the laboratory qualifies for one of the approved exceptions:

- Laboratories that are not at a fixed location; that is, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the certificate of the designated primary site or home base, using its address.
- Not-for-profit or Federal, State or local government laboratories that engage in limited public health testing (not more than a combination of 15 moderately complex or waived tests per certificate) may file a single application.

- Laboratories within a hospital that are located at contiguous buildings on the same campus and under common direction may file a single application for the laboratory sites within the same physical location or street address.

Specimen collection is not subject to CLIA Regulations. All other tests require the appropriate certificate according to CLIA classification. CMS maintains the following lists:

A. Tests Granted Waived Status Under CLIA
B. Provider-performed Microscopy Procedures

Current versions of the list can be found on the internet at www.cms.gov/CLIA.

3.0 DOCUMENTATION AND VERIFICATION OF CLIA CERTIFICATION

Documentation of CLIA compliance for all on-site and reference laboratories is maintained at KHS in the Provider Network Management credentialing system. Copies of valid CLIA certificates are maintained in the electronic provider files.

3.1 Initial Verification & Recredentialing

Providers must include a copy of their current CLIA certificate in their credentialing and recredentialing application packages.

3.2 On-going Verification

Facility inspection will include confirmation that CLIA requirements are met, if applicable during facility site review. Facilities subject to CLIA will not be approved without confirmation that these requirements have been satisfied. Copies of valid CLIA certificates with the certificate type must be kept on file in the provider's office and provided upon request to the Provider Network Management Credentialing staff upon renewal.

REFERENCE:

[1] **Revision 2020-05:** Recommended by QI to be moved to PNM; PNM Revisions based on credentialing requirements; Policy updated to reflect current CMS/CLIA Regulations CMS.Gov. **Revision 2017-04:** Three year review requested by Compliance. **Revision 2014-10:** Policy reformatted. Policy provided to QI Supervisor for review and/or revision.
[2] DHS Contract Section 3.25