



KERN HEALTH SYSTEMS


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POLICY AND PROCEDURES			
SUBJECT: Clinical Laboratory Improvements Amendments (CLIA) Certification Requirements		POLICY #: 2.23-P	
DEPARTMENT: Health Services - Quality Improvement			
Effective Date: 02/2002	Review/Revised Date: 05/25/2017	DMHC	PAC
		DHCS	QI/UM COMMITTEE
		BOD	FINANCE COMMITTEE



 Douglas A. Hayward
 Chief Executive Officer


Date 5/25/17

 Chief Medical Officer

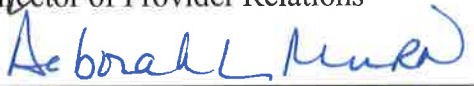


 Chief Operating Officer

Date _____



 Director of Provider Relations



 Administrative Director of Health Services

Date 5/9/17

Date 4/18/17

Date 4/14/17

POLICY¹:

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 staffed and for each subcontractor site or reference laboratory where laboratory services are performed for KHS members. The CLIA law requires any laboratory

performing testing on specimens derived from a human being for purposes of providing diagnosis, treatment, etc. to enroll with the CLIA program².

2.0 TYPES OF CLIA CERTIFICATION AND ALLOWED PROCEDURES

The following types of CLIA certification are available:

- A. **Certificate of Waiver** – holders may only perform waived tests.
- B. **Certificate for Provider-Performed Microscopy (PPM) Procedures** – allows a physician, midlevel practitioner, or dentist to perform PPM procedures and waived tests.
- C. **Certificate of Registration** - allows a laboratory to conduct moderate and/or high complexity laboratory testing until the entity is determined by survey to be in compliance with the CLIA regulations.
- D. **Certificate of Compliance** - issued to a laboratory after an inspection finds the laboratory to be in compliance with all applicable CLIA requirements. Allows a laboratory to conduct 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 moderate and/or high complexity testing.

2.1 Procedures Subject to CLIA

The law requires that all laboratories performing testing must have a CLIA certificate. Specimen collection is not subject to CLIA. 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 headquarters. Copies of valid CLIA certificates are maintained in the provider files.

3.1 Initial Verification

Providers must include a copy of their current CLIA certificate in their credentialing application package.

3.2 On-going Verification

Facility inspection will include confirmation that CLIA requirements are met. 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 be provided upon request. The Quality Improvement (QI) Registered Nurse (RN) site review team includes CLIA Certificate copies in the site review file. Certificate copies obtained during site review are forwarded by QI staff to the Provider Relations Department.

REFERENCE:

¹ **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