

Informational Bulletin Regarding Acceptable Clinical Laboratory Improvement Amendment (CLIA) Certificates

California Code of Regulations (CCR), Title 22, Section 51000.30(d)(19) provides that applicants who provide clinical laboratory or laboratory services are required to submit with their application a Centers for Medicare & Medicaid Services (CMS) Clinical Laboratory Improvement Amendment (CLIA) certificate appropriate for the level of testing performed and a state license or registration. The CLIA certificate is required by the Department of Health Care Services (DHCS) Provider Enrollment Division (PED) to allow clinical laboratories or laboratories to bill for tests that the provider is authorized to perform.

Pursuant to CCR, Title 22, Section 51000.30(d)(19), applicants are required to submit a CLIA Certificate of Compliance or Certificate of Accreditation that includes a list of the laboratory specialties/subspecialties the applicant is certified to perform and their effective dates. A CLIA Certificate of Registration does not meet the requirements of CCR, Title 22, Section 51000.30(d)(19) or its equivalent.

A complete application package for a clinical laboratory, providing clinical laboratory services, consists of a [Medi-Cal Clinical Medical Laboratory Application](#) (DHCS 6204), a [Medi-Cal Disclosure Statement](#) (DHCS 6207), a [Medi-Cal Provider Agreement](#) (DHCS 6208), a CLIA Certificate of Compliance or CLIA Certificate of Accreditation for the business address on the application, a California Clinical Lab License or Registration and all other required documentation.

An application package for a change of location or change of ownership of those providing clinical laboratory services must also include proof of the change of location (such as, a letter from CMS confirming that a site visit of the new location has taken place) or proof of change of ownership (such as, bill of sale, sales or merger agreement, or articles of incorporation).

As defined in CCR, Title 22, Section 51137.1, a clinical laboratory or laboratory is *“any place used, organized, or operated, for the examination, detection, identification, measurement, or enumeration of any particular entity or substance, which consists of materials derived from the human body for the purpose of providing information for diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings, or used as an aid in the prevention, prognosis, monitoring, or treatment of a physiological or pathological condition in a human being.”*

As defined in CCR, Title 22, Section 51137.2, clinical laboratory or laboratory services include *“the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other types of examination of materials derived from the human body, for purposes of diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.”*