

17 CA ADC § 1039.1

17 CCR § 1039.1

Cal. Admin. Code tit. 17, § 1039.1

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Title 17. Public Health

Division 1. State Department of Health Services (Refs & Annos)

Chapter 2. Laboratories (Refs & Annos)

Subchapter 1. Service Laboratories

Group 2. Clinical Laboratory Regulations

Article 2.8. Clia Certification/State Licensure

➔§ 1039.1. Recognition of CLIA Certification for Limited Purpose and Period.

(a) Except for a certificate of accreditation issued by HHS, a CLIA certificate issued to a clinical laboratory that on December 31, 1995 was not required to obtain a state license pursuant to Section 1241 of Chapter 3, shall be considered to be a state license or registration issued pursuant to Chapter 3 until such time as CLIA exempt status is obtained, provided that the CLIA certificate is for the type and complexity of clinical laboratory tests or examinations performed and that it remains in effect, unsuspended and unrevoked during the entire period covering January 1, 1996 to when CLIA exempt status is granted by HHS.

(b) A certificate of accreditation issued by HHS to a clinical laboratory that on December 31, 1995 was not required to obtain a state license pursuant to Section 1241 of Chapter 3, shall be considered a state license or registration issued pursuant to Chapter 3 until such time as the accreditation body, upon whose accreditation the certificate of accreditation was issued by HHS, fails to be approved by the department as having accreditation standards that are equal to, or more stringent than, state requirements for licensure; and, provided that:

(1) The certificate of accreditation issued by HHS is for the type and complexity of clinical laboratory tests or examinations performed and that it remains in effect, unsuspended and unrevoked; and

(2) After exempt status is obtained, the accredited laboratory pays the department the \$100 annual certificate of accreditation renewal fee.

(c) A certificate of waiver issued by HHS, to a clinical laboratory that on December 31, 1995 was required to obtain a state license, and that performs only waived tests, physician performed microscopy, or both, shall be considered to be a state registration issued pursuant to Chapter 3 until such time as CLIA exempt status is obtained, provided that the certificate of waiver remains in effect, unsuspended and unrevoked during the entire period covering January 1, 1996 to when CLIA exempt status is granted by HHS.

Note: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code. Reference: Sections 1206, 1220, 1241, 1265, 1281 and 1288.5, Business and Professions Code.

HISTORY

1. New article 2.8 (sections 1039.1-1039.3) and section filed 5-28-96 as an emergency; operative 5-28-96 (Register 96, No. 22). A Certificate of Compliance must be transmitted to OAL by 9-25-96 or emergency language will be repealed by operation of law on the following day.

2. New article 2.8 (sections 1039.1-1039.3) and section refiled 10-7-96 as an emergency, including amendment of subsections (a) and (c); operative 10-7-96 (Register 96, No. 41). A Certificate of Compliance must be transmitted to OAL by 2-4-97 or emergency language will be repealed by operation of law on the

following day.

3. Certificate of Compliance as to 10-7-96 order, including amendment of subsection (b), transmitted to OAL 2-3-97 and filed 3-19-97 (Register 97, No. 12).

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