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Title 22@ Social Security

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Division 3@ Health Care Services

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Subdivision 1@ California Medical Assistance Program

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Chapter 3@ Health Care Services

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Article 3@ Standards for Participation

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Section 51211.2@ Laboratory or Clinical Laboratory

51211.2 Laboratory or Clinical Laboratory

(a)

A laboratory or clinical laboratory in California or receiving biological specimens (as defined in Business and Professions Code section 1206) originating in California shall:(1) Be operated under a current, unrevoked and unsuspended clinical laboratory license or registration issued by the department pursuant to division 2, chapter 3, (commencing with section 1200) of the Business and Professions Code; or a current, unrevoked and unsuspended certificate of approval issued by the department pursuant to sections 1000-1003 inclusive of the Health and Safety Code; or be exempt from licensure and registration under Business and Professions Code section 1241 or 1244; and (2) Have a current, unrevoked and unsuspended, certificate appropriate for the type and complexity of clinical laboratory tests or examinations performed, issued pursuant to the federal Clinical Laboratory Improvement Amendments (CLIA) of 1988, 42 United States Code section 263a; P.L. 100-578 and its implementing regulations, 42, Code of Federal Regulations part 493. If the United States Department of Health and Human Services (HHS) exempts clinical laboratories, laboratories or public health laboratories licensed, registered or otherwise approved by the department from the requirements of CLIA pursuant to (p) of section 263 a of title 42 of the United States Code and section 493.513 of title 42 of the Code of Federal Regulations, this subsection's requirements regarding a CLIA certificate shall not apply, but only to

those clinical laboratories, laboratories or public health laboratories exempted by HHS and only for the period of such exemption. (3) If providing services to persons who are Medicare eligible, be certified or meet the requirements for certification under title XVIII of the Federal Social Security Act, and have elected to provide services under title XVIII, or (4) If providing services to persons who are not Medicare eligible, be certified or meet the requirements for certification under title XVIII of the Federal Social Security Act.

(1)

Be operated under a current, unrevoked and unsuspended clinical laboratory license or registration issued by the department pursuant to division 2, chapter 3, (commencing with section 1200) of the Business and Professions Code; or a current, unrevoked and unsuspended certificate of approval issued by the department pursuant to sections 1000-1003 inclusive of the Health and Safety Code; or be exempt from licensure and registration under Business and Professions Code section 1241 or 1244; and

(2)

Have a current, unrevoked and unsuspended, certificate appropriate for the type and complexity of clinical laboratory tests or examinations performed, issued pursuant to the federal Clinical Laboratory Improvement Amendments (CLIA) of 1988, 42 United States Code section 263a; P.L. 100-578 and its implementing regulations, 42, Code of Federal Regulations part 493. If the United States Department of Health and Human Services (HHS) exempts clinical laboratories, laboratories or public health laboratories licensed, registered or otherwise approved by the department from the requirements of CLIA pursuant to (p) of section 263 a of title 42 of the United States Code and section 493.513 of title 42 of the Code of Federal Regulations, this subsection's requirements regarding a CLIA certificate shall not apply, but only to those clinical laboratories, laboratories or public health laboratories exempted by HHS and only for the period of

such exemption.

(3)

If providing services to persons who are Medicare eligible, be certified or meet the requirements for certification under title XVIII of the Federal Social Security Act, and have elected to provide services under title XVIII, or

(4)

If providing services to persons who are not Medicare eligible, be certified or meet the requirements for certification under title XVIII of the Federal Social Security Act.

(b)

All persons performing, supervising, consulting on, or directing laboratory or clinical laboratory services in California or on biological specimens originating in California shall comply with the requirements set forth in division 2, chapter 3 (commencing with section 1200) of the Business and Professions Code and the regulations adopted thereunder for the type and complexity of testing performed.

(c)

For the purposes of providing laboratory services for qualified practitioners whose practices are conducted solely in states other than California and on biological specimens that do not originate in California, a laboratory or clinical laboratory shall be certified to provide services under the federal Clinical Laboratory Improvement Amendments (CLIA) of 1988, 42 United States Code section 263a; P.L. 100-578 and shall be licensed, registered or otherwise approved by the appropriate state agency in the state in which it is located, if such licensure, registration or approval is required.