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CALIFORNIA. LAWS, STATUTES, ETC.
CLINICAL LABORATORY ACT

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The Clinical Laboratory Act

(Business and Professions Code, Division 2, Chapter 3, Sections 1200 to 1305 inclusive. Chapter 804, Statutes of 1937, codified Statutes of 1941)

and

Regulations of the State Board of Health Pertaining to Clinical Laboratories



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The Clinical Laboratory Act and Regulations of the California
State Board of Public Health Pertaining to
Clinical Laboratories

THE CLINICAL LABORATORY ACT

(Business and Professions Code, Division 2, Chapter 3, Sections 1200 to
1305 inclusive. Chapter 804, Statutes of 1937, codified
Statutes of 1941)

CHAPTER 3. CLINICAL LABORATORY TECHNOLOGY

Article 1. General Provisions

1200. Every provision of this chapter shall be liberally construed to protect the interests of all persons affected. Construction

1201. As used in this chapter, "person" includes firm, association and corporation. "Person"

1202. As used in this chapter, "board" means the State Board of Health. "Board"

1203. As used in this chapter, "clinical laboratory technologist" means any person who engages in the work and direction of a clinical laboratory. "Clinical laboratory technologist"

1204. As used in this chapter, "clinical laboratory technician" means any person other than a physician and surgeon who, under the direction of a clinical laboratory technologist or a physician and surgeon, performs the technical procedure called for in a clinical laboratory. "Clinical laboratory technician"

1205. As used in this chapter, "clinical laboratory" means any place, establishment or institution organized and operated for the practical application of one or more of the fundamental sciences by the use of specialized apparatus, equipment and methods for the purpose of obtaining scientific data which may be used as an aid to ascertain the presence, progress and source of disease. "Clinical laboratory"

Article 2. Administration and Regulation

1220. The board shall by regulation require that all clinical laboratories be conducted, maintained and operated without injury to the public health. Regulation of clinical laboratories

1221. The board may employ special examiners, and may make regulations for the conduct of examinations under this chapter. Examinations

1222. The board shall by regulation provide for the exemption from the licensing provisions of this chapter of one or more apprentice technicians in each laboratory. Apprentice technicians

1223. The board shall make all other regulations necessary for the enforcement of this chapter. Enforcement regulations

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Inspection 1224. Agents of the board may inspect and inquire into the methods and equipment used by clinical laboratories operating under this chapter. The board shall, when such methods or equipment are in its judgment a menace to public health, make recommendations for change to the director in charge.

Reports of board 1225. The board shall, within 30 days prior to the regular session of the Legislature, submit to the Governor a full and true report of transactions under this chapter during the preceding biennium, including a complete statement of receipts and expenditures during the period.

Article 3. Application of the Chapter

Scope of chapter 1240. This chapter does not authorize any person to practice medicine and surgery or to furnish the services of physicians for the practice of medicine and surgery. This chapter does not repeal or in any manner affect any provision of this code relating to the practice of medicine.

Exceptions 1241. * This chapter does not apply to a clinical laboratory operated by any of the following:

(a) Nonprofit hospitals.

(b) Nonprofit hospital associations.

(c) Any nonprofit hospital department which is chiefly maintained by dues or contributions from employees of a common employer or a group of affiliated employers, the services of which are principally confined to such employees, their dependents and members of their families and persons disabled in or by reason of the operations of the employer or group of employers.

(d) The State of California, or the United States of America, or any department, official or agency thereof.

(e) Nonprofit foundations engaged in research work.

Article 4. Licensing

Clinical laboratory technologist's license 1260. The board shall issue a clinical laboratory technologist's license to each person who holds a degree in one or more of the fundamental sciences issued by a recognized institution and whom the board finds by written, oral and practical examination to be properly qualified.

Clinical laboratory technicians' license 1261. The board shall issue a clinical laboratory technician's license to each person found by it to be properly qualified and it may hold examinations either written, oral or practical, to aid it in judging the qualifications of applicants.

Temporary licenses 1262. The board may issue a temporary clinical laboratory technologist's license or a temporary clinical laboratory technician's license, to cover a period sufficient for the giving of examinations, or for the determination of the qualifications of applicants.

* Section 1241 has been declared unconstitutional by the State Attorney General except for subsection (d) (NS686).

1263. Licenses issued under this chapter may cover work in any one basic science, or may cover proficiency in the entire field of clinical laboratory work. Scope of licenses

1264. Any person maintaining, conducting or operating a clinical laboratory shall display in a prominent place in the clinical laboratory, the license of each person supervising and directing the clinical laboratory. Display of licenses

1265. A license under this chapter may be revoked by the board for good cause after hearing on notice. Revocation

Article 5. Offenses Against the Chapter

1280. It is unlawful for any person to act as a clinical laboratory technologist unless he is licensed in that capacity under this chapter. Necessity of license

1281. It is unlawful for any person to act as a clinical laboratory technician unless he is licensed in that capacity under this chapter. Same

1282. It is unlawful for any person to make any test or examination in a clinical laboratory which requires the application of one or more of the fundamental sciences such as bacteriology, biochemistry, serology and parasitology, unless the person is one of the following: Unlawful to make tests

(a) A licensed clinical laboratory technician in the subject or subjects concerned with the test or examination.

(b) A licensed clinical laboratory technologist.

(c) A physician and surgeon licensed under the chapter on medicine of this code.

1283. It is unlawful for any person to conduct, maintain or operate a clinical laboratory unless such clinical laboratory is under the immediate supervision and direction of one of the following: Supervision

(a) A licensed clinical laboratory technologist.

(b) A physician and surgeon licensed under the chapter on medicine of this code.

1284. It is unlawful for any person conducting, maintaining or operating a clinical laboratory to employ any technician except a licensed clinical laboratory technician or an apprentice technician exempted from the licensing provisions of this chapter under the regulations of the board. Unlawful employment

1285. It is unlawful for an apprentice technician to work or be employed in a clinical laboratory unless there are on the active laboratory staff one or more licensed clinical laboratory technicians. Apprentices

1286. It is unlawful for more than two apprentice technicians to work or be employed at the same time in the same clinical laboratory. Same

1287. Any person who violates this chapter is guilty of a misdemeanor. Penalty

Article 6. Revenue

- Fees** 1300. The amount of application and license fee under this chapter shall be fixed by the board, subject to the following:
- (a) The application fee for a clinical laboratory technologist's license shall not exceed ten dollars (\$10).
 - (b) The annual fee for a clinical laboratory technologist's license shall not exceed ten dollars (\$10).
 - (c) The application fee for a clinical laboratory technician's license shall not exceed five dollars (\$5).
 - (d) The annual fee for a clinical laboratory technician's license shall not exceed one dollar (\$1).
- Calendar year** 1301. The application fee required by this chapter covers the issuance of the license and the license fee for the remainder of the calendar year during which the license is issued.
- Fee not to be returned** 1302. If any applicant fails an examination given under this chapter no part of the application fee shall be returned.
- Time of payment** 1303. The annual fee set under this chapter shall be paid within 60 days after the commencement of each calendar year. Failure to pay the annual license fee within 60 days after the commencement of the year in which it is due shall automatically cancel any license issued under this chapter, subject, however, to reinstatement under such rules and regulations as the board may make therefor.
- Report by board** 1304. All fees set under this chapter shall be collected by and paid to the board. Within 10 days after the beginning of each month the board shall report to the State Controller the amounts and sources of the collections made under this chapter during the preceding month, and at the same time, all such moneys shall be paid into the State Treasury.

REGULATIONS OF THE STATE BOARD OF HEALTH PERTAINING TO CLINICAL LABORATORIES

*Rule 1. Examinations for Technologists' Licenses

The examinations for certificate and license as clinical laboratory technologist shall be given in the four subjects of bacteriology, serology, biochemistry (including hematology) and parasitology. The prerequisites for admission to the examination shall be either of the following:

Either: (a) provide proof satisfactory to the department that the applicant is a lawful holder of a degree of Bachelor of Arts or Bachelor of Science or equivalent degree as approved by the department, from a college or university approved by the department. The major work for such degree shall be in the fundamental medical sciences with major work in one or more of the following subjects: medical technology, biochemistry, bacteriology or parasitology or equivalent subjects as may be determined by the department, and

* Amended Rules 1 and 2 became effective August 30, 1945.

such university work including resident standard courses in inorganic and organic chemistry, biology, physics, medical bacteriology, serology, biochemistry, hematology and medical parasitology, and a minimum of five years' experience after graduation from college as a technician doing clinical laboratory work embracing the various fields of clinical laboratory activity in a clinical laboratory approved by the department.

Or: (b) a minimum of ten years' experience as a responsible technician doing clinical laboratory work embracing the various fields of clinical laboratory activity in a clinical laboratory approved by the department, except that university work which includes courses in the fundamental sciences may be substituted to a maximum of four years for such experience in the ratio of 30 semester hours for each year of experience.

*** Rule 2. Examinations for Technicians' Licenses**

The examinations for licenses to work in a clinical laboratory as a technician shall cover the field of the four subjects of bacteriology, serology, biochemistry (including hematology) and parasitology. If the examination is passed the applicant will receive a certificate and license entitling the holder to engage in any and all the activities of a clinical laboratory.

The prerequisites for entrance into the examination shall be either of the following:

Either: (a) Completion of a regular four-year college curriculum in medical or clinical laboratory technic with a degree of A.B. or B.S. in a college or university approved by the department, the last year of which course shall have been primarily clinical laboratory procedure.

Or: (b) Graduation from college with a degree of A.B. or B.S. and a major in bacteriology, biochemistry or essentially equivalent subject or subjects as may be determined by the department plus one year of apprenticeship training in a clinical laboratory approved by the department. A year apprenticeship training in a public health laboratory may be accepted if the apprenticeship or university course included practical work in clinical biochemistry and hematology.

Or: (c) A minimum of five years' experience as a technician or apprentice doing clinical laboratory work embracing the various fields of clinical laboratory activity in a clinical laboratory approved by the department, except that university work which includes courses in the fundamental sciences may be substituted to a maximum of four years for such experience in the ratio of 30 semester hours for each year of experience; provided, however, that until January 1, 1948, a minimum of three years' experience as defined in this section shall be considered as fulfilling the requirements and provided further that until January 1, 1948, three years of college with major work in the physical or biological sciences shall be credited as one year's experience.

*** Rule 3. Supervision of More Than One Laboratory by One Person**

No person licensed to operate a clinical laboratory shall operate more laboratories than he can actually supervise by personal daily visits.

Rule 4. Apprentices

(a) Clinical laboratory directors may receive into the laboratory for purposes of instruction individuals who are as yet untrained in laboratory procedures and may use their services in any proper manner, but apprentices shall not be intrusted with any examinations excepting under the immediate supervision of the technologist or physician director of the laboratory or of a licensed technician.

No clinical laboratory may receive or employ an unlicensed person under that provision of Section 1222 of the Business and Professions Code applying to apprentices unless provision adequate in the opinion of the director is made for a reasonable amount of didactic instruction during the apprenticeship and the opportunity to become familiar with all the procedures used in the laboratory. No laboratory may accept persons for apprenticeship unless the field of activities of that laboratory includes all of the following activities: blood cultures, blood counts, blood differential counts, blood sugar and urea estimations, hemaglobin estimations, gastric analyses, urine analyses, urine sediment examinations, microscopic examination of feces, serological precipitation and agglutination tests, metabolism tests.

(b) The number of apprentices in a laboratory shall not exceed the following ratios to technicians:

- (1) A laboratory having not more than one fully licensed technician may have one apprentice only.
- (2) A laboratory with two or more fully licensed technicians or technologists may have two apprentices.

(c) Apprentices shall not be left in charge of a laboratory or given authority to make any examinations or tests during the absence of the technologist or physician and a licensed technician unless such licensed technician, licensed physician or technologist be within immediate call on the premises. The making of tests by apprentices in the absence of the technologist or physician and a licensed technician with their knowledge or consent shall be cause for revocation of the license of the person in charge.

(d) Any person holding a limited license without examination or holding certificates in less than three subjects shall be considered as occupying the status of an apprentice in work for which he does not hold a license. The presence of such a partially certified person in a laboratory does not conflict with Section (b) relating to the number of apprentices. Limited licenses secured without examination do not entitle the holder to work in a city or county public health laboratory.

* *Note.*—The title of the act states that its purpose is the protection of the public health. The requirement of a technologist's or a physician's license for the conduct of a laboratory is evidence that this was considered necessary to insure competent supervision. Competent supervision is therefore a basic purpose of the act. In the opinion of the department competent supervision can not be maintained without personal contact.

(e) The discontinuance of an apprentice, and also the acquisition of a new apprentice, must be reported to the State Division of Laboratories, giving the name of such apprentice and the date of severance or commencement, as the case may be.

Rule 5. Fees for Examinations and Certificates

(a) Clinical Laboratory Technologist.

The fee for the examination for the certificate as clinical laboratory technologist shall be \$4, payable with application and not returnable in case of failure. If the applicant passes, an additional \$6 must be paid before the certificate is issued. The annual fee for license as clinical laboratory technologist shall be \$10 for each year following the calendar year in which the certificate was issued and payable within 60 days after the commencement of each calendar year.

(b) Certificates and Licenses for Technicians.

The fee for the examination for the certificate as clinical laboratory technician shall be \$4, not returnable in case of failure. The fee for examination in single subjects is \$2 not returnable in case of failure. Technicians' licenses issued under the blanketing-in provision of Chapter 804 must be renewed annually by payment of a fee of \$1. A license in one subject obtained by examination must be renewed annually by payment of a fee of \$1; licenses in two subjects held by the same individual, \$1; licenses in three subjects, \$1.50; license as clinical laboratory technician, \$1.

Rule 6. Revocation of Certificates

Both certificates and licenses issued by the board may be revoked for the following reasons:

- (a) Failure to pay the annual renewal fee within 60 days after January 1st.
- (b) Upon proof of conduct involving moral turpitude or dishonest reporting of tests.
- (c) Upon proof that the holder has violated the rules and regulations of the State Board of Public Health.

Rule 7. Procedure for Revocation

The procedure for revocation of a certificate shall be as follows: The Chief of the Division of Laboratories or other interested person shall prepare a statement of the charges which shall be forwarded to the Director of the Department. The Director of the Department shall send a copy of the charges to the defendant by registered mail and shall set a date for a hearing of the charges before the State Board of Public Health and shall give the person whose certificate is in question notice of such hearing at least 10 days in advance thereof. The findings of the board may be:

Censure and warning.

(2) Revocation of certificate and license.

The Chief of the Division of Laboratories shall notify all persons who have not paid their renewal fees by March 1st, that their right to operate under their license has lapsed and will not be restored until written application has been made and the fee for the current year plus \$5 delinquent

fee has been paid, except that prior to July 1, 1943, reinstatement shall be granted upon application by payment of the fee for the current year only. In case the license is allowed to lapse for a period of more than one year the reinstatement fee shall be \$5 for each year the fee has been allowed to lapse plus payment of all lapsed renewal fees, both beginning with the year 1943 provided, however, that licentiates serving in the armed forces of the United States whose fees have lapsed during the period of their services with the armed forces, shall be reinstated within 60 days after the termination of their services with the armed forces upon written application and payment of the then current year's fees.

Rule 8. Personnel Report

All clinical laboratory directors shall transmit to the Chief of the State Division of Laboratories, semiannually, on the first of July and the first of January the names of all persons employed in the laboratory showing whether full or part time and their classification as to title, certificates held and duties performed.

Rule 9. Display of License

Each technician and each technologist shall display his or her certificate of licensure in the laboratory where employed in the work and no certificate shall be displayed after cancellation or expiration.

Rule 10. Lapse of License


When any person licensed by the State Department of Public Health for work in clinical laboratories gives up active work under the license held by him and remains inactive for a period of five years, the license shall lapse and the person shall not be relicensed except by recommendation of the technician's examination committee who may require an interview. The payment of fees for annual renewal of license during the interval of the absence from the work shall not relieve the person from the necessity of appearing before the committee.

Rule 11. Written Examination Required ; Provision for Temporary License

No certificate of licensure as clinical laboratory technician or technologist shall be issued except after written examinations which are preferably supplemented by practical examinations, provided that, when delay in meeting these requirements would work a hardship, a temporary license may be issued to a technician who by training or experience is apparently qualified. However, such a license will be good only until the next regular examination and may be renewed only upon specific authorization by the Board of Health.



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