BUSINESS AND PROFESSIONS CODE - BPC

DIVISION 2. HEALING ARTS [500 - 4999.129] *(Division 2 enacted by Stats. 1937, Ch. 399.)*

CHAPTER 3. Clinical Laboratory Technology [1200 - 1327] *(Chapter 3 repealed and added by Stats. 1951, Ch. 1727.)*

ARTICLE 2. Administration and Regulation [1220 - 1228] *(Article 2 added by Stats. 1951, Ch. 1727.)*

1220. (a) (1) Each clinical laboratory shall maintain records, equipment, and facilities that are adequate and appropriate for the services rendered.

(2) (A) Except for tests or examinations classified as waived under CLIA, each clinical laboratory shall enroll, and demonstrate successful participation, as defined under CLIA, for each specialty and subspecialty in which it performs clinical laboratory tests or examinations, in a proficiency testing program approved by the department or by HCFA, to the same extent as required by CLIA in Subpart H (commencing with Section 493.801) of Title 42 of the Code of Federal Regulations. This requirement shall not be interpreted to prohibit a clinical laboratory from performing clinical laboratory tests or examinations in a specialty or subspecialty for which there is no department or HCFA approved proficiency testing program.

(B) Each clinical laboratory shall authorize its proficiency test results to be reported to the department in an electronic format that is compatible with the department's proficiency testing data monitoring system and shall authorize the release of proficiency tests results to the public to the same extent required by CLIA.

(b) Each clinical laboratory shall be conducted, maintained, and operated without injury to the public health.

(c) (1) The department shall conduct inspections of licensed clinical laboratories no less than once every two years. The department shall maintain a record of those inspections and shall ensure that every licensed clinical laboratory in California is inspected at least that often.

(2) Registered clinical laboratories shall not be routinely inspected by the department.

(3) The department shall conduct an investigation of complaints received concerning any clinical laboratory, which may include an inspection of the laboratory.

(4) Each licensed or registered clinical laboratory shall be subject to inspections by HCFA or HCFA agents, as defined by CLIA, as a condition of licensure or registration.

(d) (1) Each clinical laboratory shall perform all clinical laboratory tests or examinations classified as waived under CLIA in conformity with the manufacturer's instructions.

(2) Except for those clinical laboratories performing only tests or examinations classified as waived under CLIA, each clinical laboratory shall establish and maintain all of the following:

(A) A patient test management system that meets the standards of CLIA in Subpart J (commencing with Section 493.1100) of Title 42 of the Code of Federal Regulations.

(B) A quality control program that meets the requirements of CLIA in Subpart K (commencing with Section 493.1200) of Title 42 of the Code of Federal Regulations as in effect on January 1, 2015, and that may include the clinical laboratory's use of the following alternative quality control testing procedures recognized by the federal Centers for Medicare and Medicaid Services (CMS):

(i) Until December 31, 2015, equivalent quality control procedures.

(ii) Commencing January 1, 2016, an Individualized Quality Control Plan, as incorporated in Appendix C of the State Operations Manual adopted by CMS.

(C) A comprehensive quality assurance program that meets the standards of CLIA in Subpart P (commencing with Section 493.1701) of Title 42 of the Code of Federal Regulations.

(Amended by Stats. 2015, Ch. 18, Sec. 2. (SB 75) Effective June 24, 2015.)

1220.5. (a) The Department of Health Services shall develop, and provide to all licensed clinical laboratories, a form in triplicate to be used by employees, agents, and couriers of licensed clinical laboratories to give notice when a specimen storage container has been improperly secured pursuant to Section 681.

(b) The three copies of the triplicate form shall each contain instructions so that one copy is to be attached to the unlocked specimen storage container, one copy is mailed to the Department of Consumer Affairs to be forwarded to the appropriate licensing entity pursuant to Section 1288.3, and one copy is kept by the licensed clinical laboratory for its records.

(c) This form shall be provided to all licensed clinical laboratories on and after January 1, 2001.

(Added by Stats. 1999, Ch. 748, Sec. 2. Effective January 1, 2000.)

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

(Amended by Stats. 1977, Ch. 579.)

1222. The department may approve schools that are accredited by the National Accrediting Agency for Clinical Laboratory Sciences.

(Amended by Stats. 1995, Ch. 510, Sec. 15. Effective January 1, 1996.)

1222.5. (a) The department may approve any of the following seeking to provide clinical laboratory scientist programs for instruction in clinical laboratory technique that, in the judgment of the department, will provide instruction adequate to prepare individuals to meet the requirements for licensure or performance of duties under this chapter and regulations of the department:

(1) A California licensed clinical laboratory.

(2) An accredited college or university in the United States of America.

(3) A United States military medical laboratory specialist program of at least 52 weeks duration.

(4) A laboratory owned and operated by the United States government.

(b) Upon approval by the department, clinical laboratory scientist programs approved by the department may use multiple clinical laboratories to provide training in clinical laboratory technique, provided the following conditions are met:

(1) The program may apportion the clinical training among multiple clinical laboratories in any percentage as long as the total training meets the requirements established by the department.

(2) Each clinical laboratory has been approved by the department as part of the program in accordance with regulations. The program shall notify the department in writing within 30 days of a change in clinical laboratories used by the program to provide training.

(3) The director of the approved program shall be responsible for notifying the department in advance of the start and end date of training for each trainee. The program shall coordinate with the department in meeting established requirements.

(4) The director of the approved program shall ensure that all of the department's requirements for training and affiliation are met.

(5) The program has submitted an application on forms provided by the department for approval.

(c) The department shall establish by regulation the ratio of licensed clinical laboratory scientists to licensed trainees on the staff of the clinical laboratory and the minimum requirements for training in any specialty or in the entire field of clinical laboratory science or practice. Application for approval shall be made on forms provided by the department.

(Amended by Stats. 2012, Ch. 352, Sec. 2. (SB 289) Effective January 1, 2013.)

1223. (a) The Legislature finds and declares that it is the public policy of the state to ensure that California's laboratory standards, including its laboratory personnel standards, be sustained in order to provide accurate, reliable, and necessary test results. The Legislature further finds that inspections are the most effective means of furthering this policy. It is not the intent of the Legislature to reduce in any way the resources available to the department for inspections, but rather to provide the department with the greatest flexibility to concentrate its resources where they can be most effective. It is the intent of the Legislature to provide for an inspection process that includes state-based inspection components and that determines compliance with federal and state requirements for clinical laboratories.

(b) The department shall employ, or contract for, inspectors, special agents, and investigators, and provide any clerical and technical assistance as necessary to administer this chapter and may incur other expenses as necessary.

(c) Laboratories accredited by a private, nonprofit organization shall be deemed by the department to meet state licensure or registration requirements, and shall be issued a certificate of that deemed status by the department, provided that both of the following conditions are met:

(1) The private, nonprofit organization meets all of the following requirements:

(A) Is approved by the federal Center for Medicare and Medicaid Services as an accreditation body under CLIA and provides the department with the following information:

(i) A detailed comparison of the individual accreditation or approval requirements, with the comparable condition-level requirements.

(ii) A detailed description of its inspection process, including all of the following:

(I) Frequency of inspections.

(II) Copies of inspection forms.

(III) Instructions and guidelines.

(IV) A description of the review and decisionmaking process of inspections.

(V) A statement concerning whether inspections are announced or unannounced.

(VI) A description of the steps taken to monitor the correction of deficiencies.

(iii) A description of the process for monitoring proficiency testing performance, including action to be taken in response to unsuccessful participation.

(iv) A list of all of its current California licensed or registered laboratories and the expiration date of their accreditation, licensure, or registration, as applicable.

(B) Is approved by the department as having accreditation standards that are equal to, or more stringent than, state requirements for licensure and registration.

(C) Conducts inspections of clinical laboratories in a manner that will determine compliance with federal standards and California laws to the extent that California laws provide greater protection to residents, or are more stringent than federal standards, as determined by the department. Notwithstanding any other provision of law, the department may, without taking regulatory action pursuant to Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, implement or interpret this section by means of an All Clinical Laboratories Letter (ACLL). The department shall post the ACLL on its Internet Web site so that any person may observe which California laws are more stringent than federal standards, and which accreditation bodies have been approved to conduct inspections. Public comment on the ACLL shall be accepted by the department for 30 days after posting and shall become final 45 days after the posting. Comments received shall be considered by the department. Nothing in this subdivision is intended to change existing statutory or regulatory requirements governing the operation of clinical laboratories or their personnel.

(D) Is approved by the department as meeting the requirements of this paragraph. The department shall begin accepting applications for approval, in a form and manner prescribed by the department, by January 1, 2011. The department shall make a determination on an application submitted pursuant to this subparagraph within 180 days of receiving the application.

(2) The laboratory meets all of the following requirements:

(A) Meets the accreditation standards of the private, nonprofit organization.

(B) Agrees to permit the private, nonprofit organization to provide any records or other information to the department, its agents, or contractors, as the department may require.

(C) Pays the applicable fees required under Section 1300.

(D) Authorizes its proficiency testing organization to furnish to the department and the private, nonprofit organization the results of the laboratory's participation in an approved proficiency testing program, as defined in 42 C.F.R. 493.2, for the purpose of monitoring the laboratory's proficiency testing, along with explanatory information needed to interpret the proficiency testing results, upon request of the department.

(E) Authorizes the private, nonprofit organization to release to the department a notification of every violation of condition-level requirements, including the actions taken by the organization as a result of the violation, within 30 days of the initiation of the action.

(F) Authorizes the private, nonprofit organization to give notice to the department of any withdrawal of the laboratory's accreditation.

(d) If the private, nonprofit organization described in subdivision (c) has withdrawn or revoked its accreditation of a laboratory, the laboratory shall retain its certificate of deemed status issued pursuant to subdivision (c) for 45 days after the laboratory receives notice of the withdrawal or revocation of the accreditation, or the effective date of any action taken by the department, whichever is earlier.

(e) A certificate of deemed status issued pursuant to subdivision (c) shall be renewed annually provided that the conditions for issuance specified in subdivision (c) are still met. Except as authorized under subdivision (f), the department shall not conduct routine inspections of a laboratory issued a certificate of deemed status pursuant to subdivision (c). Each application for a certificate of deemed status issued under subdivision (c) and each request for renewal of that certificate shall be accompanied by the fees set forth in Section 1300. The total of those certificate application and renewal fees collected by the department shall be sufficient to cover the cost of issuing the certificate. If the department determines that those certificate fees do not fully support the costs of these activities, it shall report that determination to the Legislature.

(f) Nothing in this section shall be construed to prohibit the exercise of the department's authority to conduct complaint investigations, sample validation inspections, or require submission of proficiency testing results to the department to ensure compliance of any clinical laboratory with state standards.

(Amended by Stats. 2009, Ch. 201, Sec. 2. (SB 744) Effective October 11, 2009.)

1224. The department may, pursuant to Chapter 3.5 (commencing with Section 11340) of Division 3 of Title 2 of the Government Code, adopt, amend, or repeal any regulations necessary for the administration or enforcement of this chapter.

(Amended by Stats. 1995, Ch. 510, Sec. 17. Effective January 1, 1996.)

1224.5. The department shall conduct a study to determine whether the persons conducting tests in physician office laboratories under paragraph (12) of subdivision (b) of, and paragraph (10) of subdivision (c) of Section 1206.5, produce accurate, reliable, and necessary test results comparable to those produced by other persons performing moderate complexity or high complexity testing, or both.

(Added by Stats. 1995, Ch. 510, Sec. 18. Effective January 1, 1996.)

1225. (a) In order to carry out this chapter, any duly authorized representative of the department may do any of the following:

(1) Enter or inspect on an announced or unannounced basis any building, premise, equipment, materials, records, or information at any reasonable time to secure compliance with, or prevent a violation of this chapter or the regulations adopted pursuant thereto.

(2) Inspect, photograph, or copy any records, reports, test results, test specimens, or other information related to the requirements of this chapter or the regulations adopted pursuant thereto.

(3) Secure any sample, photograph, or other evidence from any building or premise for the purpose of enforcing this chapter or the regulations adopted pursuant thereto.

(b) The department may cooperate with, or assist persons licensed under this chapter, or other qualified persons, in evaluating laboratory procedures and techniques necessary to achieve and maintain high quality performance in clinical laboratories.

(Amended by Stats. 1989, Ch. 927, Sec. 2.)

1226. Annually the department may compile and may thereafter publish and sell a directory of persons within the state licensed under the provisions of this chapter who hold unsuspended, unforfeited and unrevoked licenses. The directory may also contain a copy of the provisions of this chapter and regulations relating thereto and such other information as the department may determine advisable.

(Added by renumbering Section 1227 by Stats. 1970, Ch. 1377.)

1227. Every person or clinical laboratory licensed or registered under this chapter shall report to the department, within 30 days thereof, any change of name or address.

(Amended by Stats. 1995, Ch. 510, Sec. 19. Effective January 1, 1996.)

1228. The department shall appoint a multidisciplinary committee to assist, advise, and make recommendations for the establishment of rules and regulations necessary to insure proper administration and enforcement of the provisions of this chapter and to assist and advise the department in matters concerning examinations for licensees of this chapter. Appointments shall be made from lists of nominees solicited by the department and shall provide adequate and proper representation of all persons affected by this chapter. Subcommittees of the committee may be appointed consisting of committee members and consultants having particular knowledge in a subject area for the purpose of assisting the department on special administrative problems and in making recommendations to the committee for consideration in the establishment of rules and regulations. The terms of office of the members shall be determined by the department.

(Added by Stats. 1970, Ch. 1125.)