AMENDED IN SENATE MAY 14, 2009

AMENDED IN SENATE APRIL 22, 2009

SENATE BILL No. 744

Introduced by Senator Strickland

February 27, 2009

An act to amend Sections 1206, 1223, 1246, 1300, 1301, and 1302 of, and to add Section 1300.2 to, the Business and Professions Code, ~~and to amend Section 101160 of, and to add Sections 101151, 101152, 101161, 101161.5, and 101162 to, the Health and Safety Code, relating to~~ *relating to clinical* laboratories, making an appropriation therefor, and declaring the urgency thereof, to take effect immediately.

LEGISLATIVE COUNSEL'S DIGEST

SB 744, as amended, Strickland. Clinical ~~laboratories: public health~~ laboratories.

(1) Existing law provides for the licensure, registration, and regulation of clinical laboratories and various clinical laboratory personnel by the State Department of Public Health and makes a violation of those provisions a crime.

Existing law requires the department to deem certain laboratories accredited by private, nonprofit organizations as meeting state licensure or registration requirements if certain conditions are met. Under existing law, the private, nonprofit organization must, among other things, be approved by the Health Care Financing Administration (HCFA) of the federal Department of Health and Human Services and must be approved by the department as having accreditation standards that are equal to, or more stringent than, state requirements for licensure or registration. The laboratory must meet the accreditation standards of that organization

and must agree to permit the organization to provide records or other information to the department.

This bill would require the private, nonprofit organization to be approved by the federal Center for Medicare and Medicaid Services instead of HCFA, to conduct inspections of clinical laboratories in a manner that will determine compliance with existing law, as specified, and to provide the department with additional information including, among other things, a detailed description of the inspection process and a description of the process for monitoring proficiency testing performance. The bill would also require the laboratory to meet additional conditions, including authorizing the private, nonprofit organization to release specified performance testing results and notification of condition-level requirement violations or withdrawal of laboratory accreditation.

Existing law specifies various fees applicable to clinical laboratories and laboratory personnel and requires the deposit of those fees in the Clinical Laboratory Improvement Fund. Existing law requires that, upon appropriation, moneys deposited in that fund be expended by the department to administer these provisions. Existing law requires the issuance of a separate license for each laboratory location, except as specified. Among other entities, not-for-profit, or federal, state, or local government laboratories engaging in limited public health testing are authorized to apply for a single license or registration, as specified.

This bill would impose a fee for approval of each of those laboratories and would increase certain other fees applicable to laboratories and laboratory personnel. The bill would prohibit the fees imposed from exceeding the costs incurred by the department in regulating clinical laboratories and their personnel. The bill also would provide that moneys deposited in the Clinical Laboratory Improvement Fund are continuously appropriated to the department for specified purposes, thereby making an appropriation, and would prohibit the redirection of those moneys for any other purpose. *The bill would require the department, beginning in fiscal year 2013–14, to report to the Legislature on the status of its work toward receiving an exemption from federal CLIA oversight.*

Existing law provides for the renewal of a clinical laboratory license or registration and requires that the renewal fee be paid during the 30-day period before the expiration of the license or registration. Existing law specifies that failure to pay the renewal fee results in forfeiture of the license or registration after a period of 60 days from the expiration date.

This bill would require a licensee or registrant that fails to renew a license or registration before the expiration date to pay a specified delinquency fee for up to 60 days after the expiration date, in addition to the renewal fee.

~~(2) Existing law requires city and county public health laboratories and their personnel to be approved by the department and to comply with the federal Clinical Laboratory Improvement Amendments of 1988. Existing law prohibits a person from acting as a public health microbiologist in a certified public health laboratory without a certificate issued by the department, and requires the applicant to pass certain examinations in order to obtain a certificate. Existing law requires the director of a public health laboratory to be certified as a public health microbiologist and to have specified qualifications and experience.~~

~~This bill would require city and county public health laboratories to obtain a certification or registration from the department, as specified. The bill would require the laboratories, public health microbiologists, and public health laboratory directors to pay certain fees in order to be certified or registered, and would prohibit the fees imposed from exceeding the costs incurred by the department in regulating public health laboratories and their personnel. The bill would authorize the department to issue certificates to public health microbiologists and laboratory directors without examination to applicants who have passed examinations of national accrediting boards with equivalent or more stringent requirements, as specified. The bill would require that the fees collected pursuant to these provisions be deposited in the Clinical Laboratory Improvement Fund and would continuously appropriate those fees to the department, as specified.~~

~~By subjecting municipal and county laboratories to these new requirements, this bill would impose a state-mandated local program.~~

~~(3) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.~~

~~This bill would provide that, if the Commission on State Mandates determines that the bill contains costs mandated by the state, reimbursement for those costs shall be made pursuant to these statutory provisions.~~

~~(4)~~

(2) This bill would declare that it is to take effect immediately as an urgency statute.

Vote: ⅔. Appropriation: yes. Fiscal committee: yes. State-mandated local program: ~~yes~~ *no*.

The people of the State of California do enact as follows:

SECTION 1. Consistent with the intent of Senate Bill 113 of the 1995–96 Regular Session (Chapter 510, Statutes of 1995), it is the intent of the Legislature, by this act, to enact provisions in state law that ensure that the state has enforcement authority and administrative structures adequate to enforce the requirements of the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA) and state laws regulating clinical laboratories, and that will enable the state to seek approval from the United States Secretary of Health and Human Services to exempt from CLIA those clinical laboratories licensed or registered under state law.

~~SECTION 1.~~

SEC. 2. Section 1206 of the Business and Professions Code is amended to read:

1206. (a) For the purposes of this chapter the following definitions are applicable:

(1) "Biological specimen" means any material that is derived from the human body.

(2) "Blood electrolyte analysis" means the measurement of electrolytes in a blood specimen by means of ion selective electrodes on instruments specifically designed and manufactured for blood gas and acid-base analysis.

(3) "Blood gas analysis" means a clinical laboratory test or examination that deals with the uptake, transport, and metabolism of oxygen and carbon dioxide in the human body.

(4) "Clinical laboratory test or examination" means the detection, identification, measurement, evaluation, correlation, monitoring, and reporting of any particular analyte, entity, or substance within a biological specimen for the purpose of obtaining scientific data which may be used as an aid to ascertain the presence, progress, and source of a disease or physiological condition in a human being, or used as an aid in the prevention, prognosis, monitoring, or treatment of a physiological or pathological condition in a human being, or for the performance of nondiagnostic tests for assessing the health of an individual.

(5) “Clinical laboratory science” means any of the sciences or scientific disciplines used to perform a clinical laboratory test or examination.

(6) “Clinical laboratory practice” means the application of clinical laboratory sciences or the use of any means that applies the clinical laboratory sciences within or outside of a licensed or registered clinical laboratory. Clinical laboratory practice includes consultation, advisory, and other activities inherent to the profession.

(7) “Clinical laboratory” means any place used, or any establishment or institution organized or operated, for the performance of clinical laboratory tests or examinations or the practical application of the clinical laboratory sciences. That application may include any means that applies the clinical laboratory sciences.

(8) “Direct and constant supervision” means personal observation and critical evaluation of the activity of unlicensed laboratory personnel by a physician and surgeon, or by a person licensed under this chapter other than a trainee, during the entire time that the unlicensed laboratory personnel are engaged in the duties specified in Section 1269.

(9) “Location” means either a street and city address, or a site or place within a street and city address, where any of the clinical laboratory sciences or scientific disciplines are practiced or applied, or where any clinical laboratory tests or examinations are performed.

(10) “Physician office laboratory” means a clinical laboratory that is licensed or registered under Section 1265, and that is either: (A) a clinical laboratory that is owned and operated by a partnership or professional corporation that performs clinical laboratory tests or examinations only for patients of five or fewer physicians and surgeons or podiatrists who are shareholders, partners, or employees of the partnership or professional corporation that owns and operates the clinical laboratory; or (B) a clinical laboratory that is owned and operated by an individual licensed physician and surgeon or a podiatrist, and that performs clinical laboratory tests or examinations only for patients of the physician and surgeon or podiatrist who owns and operates the clinical laboratory.

(11) “Public health laboratory” means a laboratory that is operated by a city or county in conformity with Article 5

(commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code and the regulations adopted thereunder.

(12) "Specialty" means histocompatibility, microbiology, diagnostic immunology, chemistry, hematology, immunohematology, pathology, genetics, or other specialty specified by regulation adopted by the department.

(13) "Subspecialty" for purposes of microbiology, means bacteriology, mycobacteriology, mycology, parasitology, virology, molecular biology, and serology for diagnosis of infectious diseases, or other subspecialty specified by regulation adopted by the department; for purposes of diagnostic immunology, means syphilis serology, general immunology, or other subspecialty specified by regulation adopted by the department; for purposes of chemistry, means routine chemistry, clinical microscopy, endocrinology, toxicology, or other subspecialty specified by regulation adopted by the department; for purposes of immunohematology, means ABO/Rh Type and Group, antibody detection for transfusion, antibody detection nontransfusion, antibody identification, compatibility, or other subspecialty specified by regulation adopted by the department; for pathology, means tissue pathology, oral pathology, diagnostic cytology, or other subspecialty specified by regulation adopted by the department; for purposes of genetics, means molecular biology related to the diagnosis of human genetic abnormalities, cytogenetics, or other subspecialty specified by regulation adopted by the department.

(14) "Direct and responsible supervision" means both of the following:

(A) Personal observation and critical evaluation of the activity of a trainee by a physician and surgeon, or by a person licensed under this chapter other than a trainee, during the entire time that the trainee is performing clinical laboratory tests or examinations.

(B) Personal review by the physician and surgeon or the licensed person of all results of clinical laboratory testing or examination performed by the trainee for accuracy, reliability, and validity before the results are reported from the laboratory.

(15) "Licensed laboratory" means a clinical laboratory licensed pursuant to paragraph (1) of subdivision (a) of Section 1265.

(16) "Registered laboratory" means a clinical laboratory registered pursuant to paragraph (2) of subdivision (a) of Section 1265.

(17) "Point-of-care laboratory testing device" means a portable laboratory testing instrument to which the following applies:

(A) It is used within the proximity of the patient for whom the test or examination is being conducted.

(B) It is used in accordance with the patient test management system, the quality control program, and the comprehensive quality assurance program established and maintained by the laboratory pursuant to paragraph (2) of subdivision (d) of Section 1220.

(C) It meets the following criteria:

(i) Performs clinical laboratory tests or examinations classified as waived or of moderate complexity under CLIA.

(ii) Performs clinical laboratory tests or examinations on biological specimens that require no preparation after collection.

(iii) Provides clinical laboratory tests or examination results without calculation or discretionary intervention by the testing personnel.

(iv) Performs clinical laboratory tests or examinations without the necessity for testing personnel to perform calibration or maintenance, except resetting pursuant to the manufacturer's instructions or basic cleaning.

(18) "Analyte" means the substance or constituent being measured including, but not limited to, glucose, sodium, or theophyline, or any substance or property whose presence or absence, concentration, activity, intensity, or other characteristics are to be determined.

(b) Nothing in this chapter shall restrict, limit, or prevent any person licensed to provide health care services under the laws of this state, including, but not limited to, licensed physicians and surgeons, and registered nurses, from practicing the profession or occupation for which he or she is licensed.

(c) Nothing in this chapter shall authorize any person to perform or order health care services, or utilize the results of the clinical laboratory test or examination, unless the person is otherwise authorized to provide that care or utilize the results. The inclusion of a person in Section 1206.5 for purposes of performing a clinical laboratory test or examination shall not be interpreted to authorize

a person, who is not otherwise authorized, to perform venipuncture, arterial puncture, or skin puncture.

~~SEC. 2.~~

SEC. 3. Section 1223 of the Business and Professions Code is amended to read:

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.

(v) Procedures for making proficiency testing information available, including explanatory information required to interpret proficiency testing results, on a reasonable basis, upon request of any person.

(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~~, interpret, or make specific~~ *or interpret* this section by means of an All Clinical Laboratories Letter (ACLL)~~ or similar instruction~~. The department shall post the ACLL~~ or similar instruction~~ on its Internet Web site so that any person may observe which California laws~~ provide greater protection to its residents or~~ are more stringent than federal standards, and which accreditation bodies~~ impose those standards~~ *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) Agrees to permit the department or its agents or contractors to conduct random inspections of clinical laboratories accredited by it in order to validate compliance with California law.

(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 private, nonprofit organization the results of the laboratory's participation in an approved proficiency testing program 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 the laboratory's proficiency test results that constitute unsuccessful participation in an approved proficiency testing program, as defined in 42 C.F.R. 493.2, when the laboratory has failed to achieve successful participation in an approved proficiency testing program.

(F) 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.

(G) 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 accreditation 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. 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.

~~SEC. 3.~~

SEC. 4. Section 1246 of the Business and Professions Code is amended to read:

1246. (a) Except as provided in subdivisions (b) and (c), and in Section 23158 of the Vehicle Code, an unlicensed person employed by a licensed clinical laboratory may perform venipuncture or skin puncture for the purpose of withdrawing blood or for clinical laboratory test purposes upon specific authorization from a licensed physician and surgeon provided that he or she meets both of the following requirements:

(1) He or she works under the supervision of a person licensed under this chapter or of a licensed physician and surgeon or of a licensed registered nurse. A person licensed under this chapter, a licensed physician or surgeon, or a registered nurse shall be physically available to be summoned to the scene of the venipuncture within five minutes during the performance of those procedures.

(2) He or she has been trained by a licensed physician and surgeon or by a clinical laboratory bioanalyst in the proper procedure to be employed when withdrawing blood in accordance with training requirements established by the State Department of Public Health and has a statement signed by the instructing physician and surgeon or by the instructing clinical laboratory bioanalyst that the training has been successfully completed.

(b) (1) On and after the effective date of the regulations specified in paragraph (2), any unlicensed person employed by a clinical laboratory performing the duties described in this section shall possess a valid and current certification as a certified phlebotomy technician issued by the department. However, an

unlicensed person employed by a clinical laboratory to perform these duties pursuant to subdivision (a) on that date shall have until January 1, 2007, to comply with this requirement, provided that he or she has submitted the application to the department on or before July 1, 2006.

(2) The department shall adopt regulations for certification by January 1, 2001, as a certified phlebotomy technician that shall include all of the following:

(A) The applicant shall hold a valid, current certification as a phlebotomist issued by a national accreditation agency approved by the department, and shall submit proof of that certification when applying for certification pursuant to this section.

(B) The applicant shall complete education, training, and experience requirements as specified by regulations that shall include, but not be limited to, the following:

(i) At least 40 hours of didactic instruction.

(ii) At least 40 hours of practical instruction.

(iii) At least 50 successful venipunctures.

However, an applicant who has been performing these duties pursuant to subdivision (a) may be exempted from the requirements specified in clauses (ii) and (iii), and from 20 hours of the 40 hours of didactic instruction as specified in clause (i), if he or she has at least 1,040 hours of work experience, as specified in regulations adopted by the department.

It is the intent of the Legislature to permit persons performing these duties pursuant to subdivision (a) to use educational leave provided by their employers for purposes of meeting the requirements of this section.

(3) Each certified phlebotomy technician shall complete at least three hours per year or six hours every two years of continuing education or training. The department shall consider a variety of programs in determining the programs that meet the continuing education or training requirement.

(4) He or she has been found to be competent in phlebotomy by a licensed physician and surgeon or person licensed pursuant to this chapter.

(5) He or she works under the supervision of a licensed physician and surgeon, licensed registered nurse, or person licensed under this chapter, or the designee of a licensed physician and surgeon or the designee of a person licensed under this chapter.

(6) The department shall adopt regulations establishing standards for approving training programs designed to prepare applicants for certification pursuant to this section. The standards shall ensure that these programs meet the state's minimum education and training requirements for comparable programs.

(7) The department shall adopt regulations establishing standards for approving national accreditation agencies to administer certification examinations and tests pursuant to this section.

(8) The department shall charge fees for application for and renewal of the certificate authorized by this section of no more than one hundred dollars ($100) *for a two-year period*.

(c) (1) (A) A certified phlebotomy technician may perform venipuncture or skin puncture to obtain a specimen for nondiagnostic tests assessing the health of an individual, for insurance purposes, provided that the technician works under the general supervision of a physician and surgeon licensed under Chapter 5 (commencing with Section 2000). The physician and surgeon may delegate the general supervision duties to a registered nurse or a person licensed under this chapter, but shall remain responsible for ensuring that all those duties and responsibilities are properly performed. The physician and surgeon shall make available to the department, upon request, records maintained documenting when a certified phlebotomy technician has performed venipuncture or skin puncture pursuant to this paragraph.

(B) As used in this paragraph, general supervision requires the supervisor of the technician to determine that the technician is competent to perform venipuncture or skin puncture prior to the technician's first blood withdrawal, and on an annual basis thereafter. The supervisor is also required to determine, on a monthly basis, that the technician complies with appropriate venipuncture or skin puncture policies and procedures approved by the medical director and required by state regulations. The supervisor, or another designated licensed physician and surgeon, registered nurse, or person licensed under this chapter, shall be available for consultation with the technician, either in person or through telephonic or electronic means, at the time of blood withdrawal.

(2) (A) Notwithstanding any other provision of law, a person who has been issued a certified phlebotomy technician certificate

pursuant to this section may draw blood following policies and procedures approved by a physician and surgeon licensed under Chapter 5 (commencing with Section 2000), appropriate to the location where the blood is being drawn and in accordance with state regulations. The blood collection shall be done at the request and in the presence of a peace officer for forensic purposes in a jail, law enforcement facility, or medical facility, with general supervision.

(B) As used in this paragraph, "general supervision" means that the supervisor of the technician is licensed under this code as a physician and surgeon, physician assistant, clinical laboratory bioanalyst, registered nurse, or clinical laboratory scientist, and reviews the competency of the technician before the technician may perform blood withdrawals without direct supervision, and on an annual basis thereafter. The supervisor is also required to review the work of the technician at least once a month to ensure compliance with venipuncture policies, procedures, and regulations. The supervisor, or another person licensed under this code as a physician and surgeon, physician assistant, clinical laboratory bioanalyst, registered nurse, or clinical laboratory scientist, shall be accessible to the location where the technician is working to provide onsite, telephone, or electronic consultation, within 30 minutes when needed.

(d) The department may adopt regulations providing for the issuance of a certificate to an unlicensed person employed by a clinical laboratory authorizing only the performance of skin punctures for test purposes.

~~SEC. 4.~~

SEC. 5. Section 1300 of the Business and Professions Code is amended to read:

1300. The amount of application, registration, and license fees under this chapter shall be as follows:

(a) The application fee for a histocompatibility laboratory director's, clinical laboratory bioanalyst's, clinical chemist's, clinical microbiologist's, clinical laboratory toxicologist's, clinical cytogeneticist's, or clinical molecular biologist's license is sixty-three dollars ($63) *commencing on July 1, 1983*.

(b) The annual renewal fee for a histocompatibility laboratory director's, clinical laboratory bioanalyst's, clinical chemist's,

clinical microbiologist's, or clinical laboratory toxicologist's license is sixty-three dollars ($63) *commencing on July 1, 1983*.

(c) The application fee for a clinical laboratory scientist's or limited clinical laboratory scientist's license is thirty-eight dollars ($38) *commencing on July 1, 1983*.

(d) The application and annual renewal fee for a cytotechnologist's license is fifty dollars ($50) *commencing on January 1, 1991*.

(e) The annual renewal fee for a clinical laboratory scientist's or limited clinical laboratory scientist's license is twenty-five dollars ($25) *commencing on July 1, 1983*.

(f) A clinical laboratory applying for a license to perform tests or examinations classified as of moderate or of high complexity under CLIA~~,~~ and a clinical laboratory applying for certification under subdivision (c) of Section 1223~~,~~ shall pay an application fee for that license or certification based on the number of tests it performs or expects to perform in a year, as follows:

(1) Less than 2,001 tests: two hundred seventy dollars ($270).

(2) Between 2,001 and 10,000, inclusive, tests: eight hundred twenty dollars ($820).

(3) Between 10,001 and 25,000, inclusive, tests: one thousand three hundred fifteen dollars ($1,315).

(4) Between 25,001 and 50,000, inclusive, tests: one thousand five hundred eighty dollars ($1,580).

(5) Between 50,001 and 75,000, inclusive, tests: one thousand nine hundred sixty dollars ($1,960).

(6) Between 75,001 and 100,000, inclusive, tests: two thousand three hundred forty dollars ($2,340).

(7) Between 100,001 and 500,000, inclusive, tests: two thousand seven hundred forty dollars ($2,740).

(8) Between 500,001 and 1,000,000, inclusive, tests: four thousand nine hundred ten dollars ($4,910).

(9) More than 1,000,000 tests: five thousand two hundred sixty dollars ($5,260) plus three hundred fifty dollars ($350) for every 500,000 tests over 1,000,000*, up to a maximum of 15,000,000 test*s.

(g) A clinical laboratory performing tests or examinations classified as of moderate or of high complexity under CLIA~~,~~ and a clinical laboratory with a certificate issued under subdivision (c) of Section 1223~~,~~ shall pay an annual renewal fee based on the

number of tests it performed in the preceding calendar year, as follows:

(1) Less than 2,001 tests: one hundred seventy dollars ($170).

(2) Between 2,001 and 10,000, inclusive, tests: seven hundred twenty dollars ($720).

(3) Between 10,001 and 25,000, inclusive, tests: one thousand one hundred fifteen dollars ($1,115).

(4) Between 25,001 and 50,000, inclusive, tests: one thousand three hundred eighty dollars ($1,380).

(5) Between 50,001 and 75,000, inclusive, tests: one thousand seven hundred sixty dollars ($1,760).

(6) Between 75,001 and 100,000, inclusive, tests: two thousand forty dollars ($2,040).

(7) Between 100,001 and 500,000, inclusive, tests: two thousand four hundred forty dollars ($2,440).

(8) Between 500,001 and 1,000,000, inclusive, tests: four thousand six hundred ten dollars ($4,610).

(9) More than 1,000,000 tests per year: four thousand nine hundred sixty dollars ($4,960) plus three hundred fifty dollars ($350) for every 500,000 tests over 1,000,000, *up to a maximum of 15,000,000 tests*.

~~(h) In addition, clinical laboratories providing cytology services shall pay an annual fee that shall be set by the department in an amount needed to meet but not exceed the department's costs of proficiency testing and special site surveys for these laboratories, and that shall be based upon the volume of cytologic slides examined by a laboratory. If the amount collected is less than or exceeds the amount needed for these purposes, the amount of fees collected from those laboratories in the following year shall be adjusted accordingly.~~

~~(i)~~

(h) The application fee for a trainee's license is thirteen dollars ($13) *commencing on July 1, 1983*.

~~(j)~~

(i) The annual renewal fee for a trainee's license is eight dollars ($8) *commencing on July 1, 1983*.

~~(k)~~

(j) The application fee for a duplicate license is five dollars ($5) *commencing on July 1, 1983*.

~~(*l*) The~~

(k) The personnel licensing delinquency fee is equal to the annual renewal fee.

~~(m)~~

(l) The director may establish a fee for examinations required under this chapter. The fee shall not exceed the total cost to the department in conducting the examination.

~~(n)~~

(m) A clinical laboratory subject to registration under paragraph (2) of subdivision (a) of Section 1265 and performing only those clinical laboratory tests or examinations considered waived under CLIA shall pay an annual fee of one hundred dollars ($100). A clinical laboratory subject to registration under paragraph (2) of subdivision (a) of Section 1265 and performing only provider-performed microscopy, as defined under CLIA, shall pay an annual fee of one hundred fifty dollars ($150). A clinical laboratory performing both waived and provider-performed microscopy shall pay an annual registration fee of one hundred fifty dollars ($150).

~~(o)~~

(n) The costs of the department in conducting a complaint investigation, imposing sanctions, or conducting a hearing under this chapter shall be paid by the clinical laboratory. The fee shall be no greater than the fee the laboratory would pay under CLIA for the same type of activities and shall not be payable if the clinical laboratory would not be required to pay those fees under CLIA.

~~(p)~~

(o) The state, a district, city, county, city and county, or other political subdivision, or any public officer or body shall be subject to the payment of fees established pursuant to this chapter or regulations adopted thereunder.

~~(q)~~

(p) In addition to the payment of registration or licensure fees, a clinical laboratory located outside the State of California shall reimburse the department for travel and per diem to perform any necessary onsite inspections at the clinical laboratory in order to ensure compliance with this chapter.

~~(r)~~

(q) The department shall establish an application fee and a renewal fee for a medical laboratory technician license, the total

fees collected not to exceed the costs of the department for the implementation and operation of the program licensing and regulating medical laboratory technicians pursuant to Section 1260.3.

~~(s)~~

(r) The costs of the department to conduct any reinspections to ensure compliance of a laboratory applying for initial licensure shall be paid by the laboratory. This additional cost for each visit shall be equal to the initial application fee and shall be paid by the laboratory prior to issuance of a license. *The department shall not charge a reinspection fee if the reinspection is due to error or omission on the part of the department.*

~~(t)~~

(s) A fee of twenty-five dollars ($25) shall be assessed for approval of each additional location authorized by paragraph (2) of subdivision (d) of Section 1265.

(t) Beginning in fiscal year 2013–14, the department shall report during the annual legislative budget hearing process on the status of the department's work toward receiving an exemption from federal CLIA oversight, any deficiencies identified by the department, and the extent to which the federal Department of Health and Human Services is accepting exemption applications and the cost to the state for an exemption. Reporting under this subdivision shall no longer be required when the state receives an exemption from the federal Department of Health and Human Services for federal CLIA oversight.

~~SEC. 5.~~

SEC. 6. Section 1300.2 is added to the Business and Professions Code, to read:

1300.2. Notwithstanding any other provision of this article, the total fees collected under this chapter shall not exceed the costs incurred by the department for licensing, certification, inspection, or other activities relating to the regulation of clinical laboratories and their personnel.

~~SEC. 6.~~

SEC. 7. Section 1301 of the Business and Professions Code is amended to read:

1301. (a) The annual renewal fee for a clinical laboratory license or registration set under this chapter shall be paid during the 30-day period before the expiration date of the license or

registration. If the license or registration is not renewed before the expiration date, the licensee or registrant, as a condition precedent to renewal, shall pay a delinquency fee equal to 25 percent of the annual renewal fee for up to 60 days after the expiration date, in addition to the annual renewal fee in effect on the last preceding regular renewal date. Failure to pay the annual renewal fee in advance during the time the license or registration remains in force shall, ipso facto, work a forfeiture of the license or registration after a period of 60 days from the expiration date of the license or registration.

(b) (1) The department shall give written notice to all persons licensed pursuant to Sections 1260, 1260.1, 1261, 1261.5, 1262, 1264, or 1270 30 days in advance of the regular renewal date that a renewal fee has not been paid. In addition, the department shall give written notice to licensed clinical laboratory bioanalysts or doctoral degree specialists and clinical laboratory scientists or limited clinical laboratory scientists by registered or certified mail 90 days in advance of the expiration of the fifth year that a renewal fee has not been paid and if not paid before the expiration of the fifth year of delinquency the licensee may be subject to reexamination.

(2) If the renewal fee is not paid for five or more years, the department may require an examination before reinstating the license, except that no examination shall be required as a condition for reinstatement if the original license was issued without an examination. No examination shall be required for reinstatement if the license was forfeited solely by reason of nonpayment of the renewal fee if the nonpayment was for less than five years.

(3) If the license is not renewed within 60 days after its expiration, the licensee, as a condition precedent to renewal, shall pay the delinquency fee identified in subdivision (*l*) of Section 1300, in addition to the renewal fee in effect on the last preceding regular renewal date. Payment of the delinquency fee will not be necessary if within 60 days of the license expiration date the licensee files with the department an application for inactive status.

~~SEC. 7.~~

SEC. 8. Section 1302 of the Business and Professions Code is amended to read:

1302. (a) There is hereby established in the State Treasury, the Clinical Laboratory Improvement Fund.

(b) All fees established under this chapter, Chapter 4 (commencing with Section 1600) of Division 2 of the Health and Safety Code, and Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code, shall be collected by and paid to the department, and shall be deposited by the department in the Clinical Laboratory Improvement Fund, along with any other moneys received by the department for the purpose of licensing, certification, inspection, proficiency testing, or other regulation of clinical laboratories, public health laboratories, blood banks, or clinical or public health laboratory personnel. Notwithstanding Section 16305.7 of the Government Code, all interest earned on moneys deposited in the fund shall be maintained in the fund.

(c) Notwithstanding Section 13340 of the Government Code, moneys deposited in the Clinical Laboratory Improvement Fund are hereby continuously appropriated to the department to administer this chapter, Chapter 4 (commencing with Section 1600) of Division 2 of the Health and Safety Code, and Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code, and shall not be redirected for any other purpose. All fees collected pursuant to this chapter shall be expended to administer this chapter. All fees collected pursuant to Chapter 4 (commencing with Section 1600) of Division 2 of the Health and Safety Code shall be expended to administer that chapter. All fees collected pursuant to Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code shall be expended to administer that article.

~~SEC. 8. Section 101151 is added to the Health and Safety Code, to read:~~

~~101151. For purposes of this article, "CLIA" means the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a; Public Law 100-578) and the regulations adopted thereunder by the federal Health Care Financing Administration and effective on January 1, 1994, or any later date, when adopted in California pursuant to subdivision (b) of Section 1208 of the Business and Professions Code.~~

~~SEC. 9. Section 101152 is added to the Health and Safety Code, to read:~~

~~101152. (a) A city or county public health laboratory shall be certified or registered with the State Department of Public Health pursuant to this section.~~

~~(b) The department shall issue a certificate or registration to a city or county public health laboratory that meets both of the following requirements:~~

~~(1) Pays the fees required under subdivision (d).~~

~~(2) Is found to be in compliance with this article, the regulations adopted hereunder, and the applicable requirements of CLIA.~~

~~(c) A certificate or registration issued to a public health laboratory shall be valid for one year.~~

~~(d) (1) A laboratory performing only those laboratory tests or examinations considered waived under CLIA shall register with the department and pay an annual registration fee of one hundred dollars ($100).~~

~~(2) A laboratory performing laboratory tests or examinations considered waived under CLIA and provider-performed microscopy, as defined under CLIA, shall register with the department and pay an annual registration fee of one hundred fifty dollars ($150).~~

~~(3) A laboratory performing clinical laboratory tests or examinations classified as of moderate or of high complexity under CLIA shall obtain a certificate from the department.~~

~~(A) The application fee for the certificate shall be based on the number of tests it performs or expects to perform in a year, as follows:~~

~~(i) Less than 2,001 tests: two hundred seventy dollars ($270).~~

~~(ii) Between 2,001 and 10,000, inclusive, tests: eight hundred twenty dollars ($820).~~

~~(iii) Between 10,001 and 25,000, inclusive, tests: one thousand three hundred fifteen dollars ($1,315).~~

~~(iv) Between 25,001 and 50,000, inclusive, tests: one thousand five hundred eighty dollars ($1,580).~~

~~(v) Between 50,001 and 75,000, inclusive, tests: one thousand nine hundred sixty dollars ($1,960).~~

~~(vi) Between 75,001 and 100,000, inclusive, tests: two thousand three hundred forty dollars ($2,340).~~

~~(vii) Between 100,001 and 500,000, inclusive, tests: two thousand seven hundred forty dollars ($2,740).~~

~~(viii) Between 500,001 and 1,000,000, inclusive, tests: four thousand nine hundred ten dollars ($4,910).~~

~~(ix) More than 1,000,000 tests: five thousand two hundred sixty dollars ($5,260) plus three hundred fifty dollars ($350) for every 500,000 tests over 1,000,000.~~

~~(B) The annual renewal fee for the certificate shall be based on the number of tests the laboratory performed in the preceding calendar year, as follows:~~

~~(i) Less than 2,001 tests: one hundred seventy dollars ($170).~~

~~(ii) Between 2,001 and 10,000, inclusive, tests: seven hundred twenty dollars ($720).~~

~~(iii) Between 10,001 and 25,000, inclusive, tests: one thousand one hundred fifteen dollars ($1,115).~~

~~(iv) Between 25,001 and 50,000, inclusive, tests: one thousand three hundred eighty dollars ($1,380).~~

~~(v) Between 50,001 and 75,000, inclusive, tests: one thousand seven hundred sixty dollars ($1,760).~~

~~(vi) Between 75,001 and 100,000, inclusive, tests: two thousand forty dollars ($2,040).~~

~~(vii) Between 100,001 and 500,000, inclusive, tests: two thousand four hundred forty dollars ($2,440).~~

~~(viii) Between 500,001 and 1,000,000, inclusive, tests: four thousand six hundred ten dollars ($4,610).~~

~~(ix) More than 1,000,000 tests: four thousand nine hundred sixty dollars ($4,960) plus three hundred fifty dollars ($350) for every 500,000 tests over 1,000,000.~~

~~SEC. 10. Section 101160 of the Health and Safety Code is amended to read:~~

~~101160. Any city or county public health laboratory established for the purposes set forth in this chapter shall meet the requirements of this article and the regulations adopted hereunder.~~

~~SEC. 11. Section 101161 is added to the Health and Safety Code, to read:~~

~~101161. (a) The State Department of Public Health shall issue a public health microbiologist certificate to each person who has applied for the certificate on forms provided by the department if that person is found to be in compliance with this article and the regulations adopted hereunder and has paid an application fee of ninety-seven dollars ($97).~~

~~(b) The department shall issue a public health laboratory director certificate to each person who has applied for the certificate on forms provided by the department if that person is found to be in compliance with this article and the regulations adopted hereunder and has paid an application fee of one hundred sixty-two dollars ($162).~~

~~(c) A certificate issued to a public health microbiologist or a public health laboratory director shall be valid for one year.~~

~~(d) A person certified as a public health microbiologist or a public health laboratory director shall, as a condition of renewal of that certificate, do both of the following:~~

~~(1) Complete 12 hours of continuing education.~~

~~(2) Pay a renewal fee of sixty-six dollars ($66) for a microbiologist certificate or one hundred sixty-two dollars ($162) for a public health laboratory director certificate.~~

~~(e) The department may issue public health microbiologist certificates or public health laboratory director certificates without examination to applicants who have passed examinations offered by a national accrediting board whose requirements are equal to or greater than those imposed by this article and the regulations established by the department.~~

~~SEC. 12. Section 101161.5 is added to the Health and Safety Code, to read:~~

~~101161.5. Notwithstanding any other provision of this article, the total fees collected under this article shall not exceed the costs incurred by the State Department of Public Health for certification, registration, inspection, or other activities relating to the regulation of public health laboratories and their personnel.~~

~~SEC. 13. Section 101162 is added to the Health and Safety Code, to read:~~

~~101162. The fees imposed pursuant to this article shall be deposited in the Clinical Laboratory Improvement Fund created under Section 1302 of the Business and Professions Code and, notwithstanding Section 13340 of the Government Code, shall be continuously appropriated to the department for expenditure for purposes of this article.~~

~~SEC. 14. If the Commission on State Mandates determines that this act contains costs mandated by the state, reimbursement to local agencies and school districts for those costs shall be made~~

~~pursuant to Part 7 (commencing with Section 17500) of Division 4 of Title 2 of the Government Code.~~

~~SEC. 15.~~

SEC. 9. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts constituting the necessity are:

In order to protect the public health by providing strong clinical laboratory oversight as soon as possible, it is necessary that this act take effect immediately.

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