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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 Clinical Laboratory Technology [1200 - 1327] (*Chapter 3 repealed and added by Stats. 1951, Ch. 1727.*)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 6. Revenue [1300 - 1302] (*Article 6 added by Stats. 1951, Ch. 1727.*)

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 genetic molecular biologist's, clinical cytogeneticist's, clinical laboratory geneticist's, or clinical reproductive biologist's license, or license for another specialty or subspecialty specified by regulation adopted by the department, is sixty-three dollars (\$63).

(b) The annual renewal fee for a license listed in subdivision (a) is sixty-three dollars (\$63).

(c) The application fee for a clinical laboratory scientist's or limited clinical laboratory scientist's license is thirty-eight dollars (\$38).

(d) The application and annual renewal fee for a cytotechnologist's license is fifty dollars (\$50).

(e) The annual renewal fee for a clinical laboratory scientist's or limited clinical laboratory scientist's license is twenty-five dollars (\$25).

(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 tests.

(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) The application fee for a trainee's license is thirteen dollars (\$13).

(i) The annual renewal fee for a trainee's license is eight dollars (\$8).

(j) The application fee for a duplicate license is five dollars (\$5).

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

(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.

(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).

(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.

(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.

(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.

(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.

(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.

(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) On or before July 1, 2013, the department shall report to the Legislature during the annual legislative budget hearing process the extent to which the state oversight program meets or exceeds federal oversight standards and the extent to which the federal Department of Health and Human Services is accepting exemption applications and the potential cost to the state for an exemption.

(Amended by Stats. 2022, Ch. 473, Sec. 10. (SB 1267) Effective January 1, 2023.)

1300.1. (a) The application and renewal fees for clinical laboratory licenses specified in Section 1300 shall be adjusted annually in the manner specified in Section 100450 of the Health and Safety Code. The adjustments shall be rounded off to the nearest whole dollar amount.

(b) This section shall become operative on January 1, 2020.

(Repealed (in Sec. 1) and added by Stats. 2017, Ch. 345, Sec. 2. (AB 658) Effective January 1, 2018. Section operative January 1, 2020, by its own provisions.)

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.

(Added by Stats. 2009, Ch. 201, Sec. 5. (SB 744) Effective October 11, 2009.)

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 Section 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 (k) 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.

(Amended by Stats. 2010, Ch. 328, Sec. 7. (SB 1330) Effective January 1, 2011.)

1301.1. Notwithstanding any other provision of this chapter, the department may establish such license periods and renewal dates for all licenses issued under this chapter in a manner as to best distribute the license renewal process throughout a given year, or longer period, if necessary, to permit the most efficient and economical use of the department's personnel and equipment. To the extent practical, provision shall be made for the proration or other fee adjustments in a manner that no licensee shall be required to pay a greater or lesser fee than he or she would have been required to pay if the change in license periods or renewal dates had not occurred.

(Added by Stats. 1990, Ch. 195, Sec. 10. Effective July 9, 1990.)

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

(b) All fees established under this chapter and Chapter 4 (commencing with Section 1600) of Division 2 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, blood banks, or clinical 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) Moneys deposited in the Clinical Laboratory Improvement Fund that are appropriated in the annual Budget Act, or any other appropriation, for support of, or expenditure by, the state department shall, upon appropriation, be expended by the state department to administer this chapter and Chapter 4 (commencing with Section 1600) of Division 2 of the Health and Safety Code. All fees collected pursuant to this chapter shall, upon appropriation, be expended to administer this chapter and shall not be redirected for any other purpose. All fees collected pursuant to Chapter 4 (commencing with Section 1600) of Division 2 of the Health and Safety Code shall, upon appropriation, be expended to administer that chapter and shall not be redirected for any other purpose.

(Amended by Stats. 2009, Ch. 201, Sec. 7. (SB 744) Effective October 11, 2009.)