

**ASSEMBLY BILL**

**No. 399**

---

---

**Introduced by Assembly Member Fox**

February 15, 2013

---

---

An act to amend Sections 1202 and 1300 of the Business and Professions Code, relating to clinical laboratories.

LEGISLATIVE COUNSEL'S DIGEST

AB 399, as introduced, Fox. Clinical laboratories.

Existing law provides for the licensure, registration, and regulation of clinical laboratories and various clinical laboratory personnel by the State Department of Public Health. Existing law prescribes various fees applicable to clinical laboratories and laboratory personnel, and requires the deposit of those fees in the Clinical Laboratory Improvement Fund. Existing law authorizes the department to collect application fees, annual renewal fees, and fees associated with enforcements, and to establish the fees for licensing examinations and for medical laboratory technician licenses.

This bill would authorize the department to charge appropriate license fees whenever it determines that a new category of licensure is necessary. This bill would also make a technical, nonsubstantive change to these provisions.

Vote: majority. Appropriation: no. Fiscal committee: yes.  
State-mandated local program: no.

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

- 1 SECTION 1. Section 1202 of the Business and Professions
- 2 Code is amended to read:

1 1202. As used in this chapter, “department” means the State  
2 Department of ~~Health Services~~ *Public Health*.

3 SEC. 2. Section 1300 of the Business and Professions Code is  
4 amended to read:

5 1300. The amount of application, registration, and license fees  
6 under this chapter shall be as follows:

7 (a) The application fee for a histocompatibility laboratory  
8 director’s, clinical laboratory bioanalyst’s, clinical chemist’s,  
9 clinical microbiologist’s, clinical laboratory toxicologist’s, clinical  
10 cytogeneticist’s, or clinical molecular biologist’s license is  
11 sixty-three dollars (\$63) commencing on July 1, 1983.

12 (b) The annual renewal fee for a histocompatibility laboratory  
13 director’s, clinical laboratory bioanalyst’s, clinical chemist’s,  
14 clinical microbiologist’s, or clinical laboratory toxicologist’s  
15 license is sixty-three dollars (\$63) commencing on July 1, 1983.

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

19 (d) The application and annual renewal fee for a  
20 cytotechnologist’s license is fifty dollars (\$50) commencing on  
21 January 1, 1991.

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

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

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

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

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

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

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

- 1 (6) Between 75,001 and 100,000, inclusive, tests: two thousand  
2 three hundred forty dollars (\$2,340).
- 3 (7) Between 100,001 and 500,000, inclusive, tests: two thousand  
4 seven hundred forty dollars (\$2,740).
- 5 (8) Between 500,001 and 1,000,000, inclusive, tests: four  
6 thousand nine hundred ten dollars (\$4,910).
- 7 (9) More than 1,000,000 tests: five thousand two hundred sixty  
8 dollars (\$5,260) plus three hundred fifty dollars (\$350) for every  
9 500,000 tests over 1,000,000, up to a maximum of 15,000,000  
10 tests.
- 11 (g) A clinical laboratory performing tests or examinations  
12 classified as of moderate or of high complexity under CLIA and  
13 a clinical laboratory with a certificate issued under subdivision (c)  
14 of Section 1223 shall pay an annual renewal fee based on the  
15 number of tests it performed in the preceding calendar year, as  
16 follows:
- 17 (1) Less than 2,001 tests: one hundred seventy dollars (\$170).
- 18 (2) Between 2,001 and 10,000, inclusive, tests: seven hundred  
19 twenty dollars (\$720).
- 20 (3) Between 10,001 and 25,000, inclusive, tests: one thousand  
21 one hundred fifteen dollars (\$1,115).
- 22 (4) Between 25,001 and 50,000, inclusive, tests: one thousand  
23 three hundred eighty dollars (\$1,380).
- 24 (5) Between 50,001 and 75,000, inclusive, tests: one thousand  
25 seven hundred sixty dollars (\$1,760).
- 26 (6) Between 75,001 and 100,000, inclusive, tests: two thousand  
27 forty dollars (\$2,040).
- 28 (7) Between 100,001 and 500,000, inclusive, tests: two thousand  
29 four hundred forty dollars (\$2,440).
- 30 (8) Between 500,001 and 1,000,000, inclusive, tests: four  
31 thousand six hundred ten dollars (\$4,610).
- 32 (9) More than 1,000,000 tests per year: four thousand nine  
33 hundred sixty dollars (\$4,960) plus three hundred fifty dollars  
34 (\$350) for every 500,000 tests over 1,000,000, up to a maximum  
35 of 15,000,000 tests.
- 36 (h) The application fee for a trainee's license is thirteen dollars  
37 (\$13) commencing on July 1, 1983.
- 38 (i) The annual renewal fee for a trainee's license is eight dollars  
39 (\$8) commencing on July 1, 1983.

- 1 (j) The application fee for a duplicate license is five dollars (\$5)  
2 commencing on July 1, 1983.
- 3 (k) The personnel licensing delinquency fee is equal to the  
4 annual renewal fee.
- 5 (l) The director may establish a fee for examinations required  
6 under this chapter. The fee shall not exceed the total cost to the  
7 department in conducting the examination.
- 8 (m) A clinical laboratory subject to registration under paragraph  
9 (2) of subdivision (a) of Section 1265 and performing only those  
10 clinical laboratory tests or examinations considered waived under  
11 CLIA shall pay an annual fee of one hundred dollars (\$100). A  
12 clinical laboratory subject to registration under paragraph (2) of  
13 subdivision (a) of Section 1265 and performing only  
14 provider-performed microscopy, as defined under CLIA, shall pay  
15 an annual fee of one hundred fifty dollars (\$150). A clinical  
16 laboratory performing both waived and provider-performed  
17 microscopy shall pay an annual registration fee of one hundred  
18 fifty dollars (\$150).
- 19 (n) The costs of the department in conducting a complaint  
20 investigation, imposing sanctions, or conducting a hearing under  
21 this chapter shall be paid by the clinical laboratory. The fee shall  
22 be no greater than the fee the laboratory would pay under CLIA  
23 for the same type of activities and shall not be payable if the  
24 clinical laboratory would not be required to pay those fees under  
25 CLIA.
- 26 (o) The state, a district, city, county, city and county, or other  
27 political subdivision, or any public officer or body shall be subject  
28 to the payment of fees established pursuant to this chapter or  
29 regulations adopted thereunder.
- 30 (p) In addition to the payment of registration or licensure fees,  
31 a clinical laboratory located outside the State of California shall  
32 reimburse the department for travel and per diem to perform any  
33 necessary onsite inspections at the clinical laboratory in order to  
34 ensure compliance with this chapter.
- 35 (q) The department shall establish an application fee and a  
36 renewal fee for a medical laboratory technician license, the total  
37 fees collected not to exceed the costs of the department for the  
38 implementation and operation of the program licensing and  
39 regulating medical laboratory technicians pursuant to Section  
40 1260.3.

1     *(r) The department may establish an application fee and a*  
2 *renewal fee for any new category of license adopted pursuant to*  
3 *Section 1208. The total fees collected shall not exceed the costs to*  
4 *the department for the implementation and operation of the*  
5 *program licensing and regulating persons issued the new category*  
6 *of license.*

7     ~~(r)~~

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

15     ~~(s)~~

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

19     ~~(t)~~

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