

AMENDED IN ASSEMBLY APRIL 25, 2016

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

**ASSEMBLY BILL**

**No. 1774**

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**Introduced by Assembly Member Bonilla**

February 3, 2016

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An act to amend Sections 654.1, 655.5, 1206, 1206.6, 1220, 1244, 1246.5, 1271.1, 1272, 1300, 1301, and 1320 of, ~~and to add Section 1272.1 to~~, to repeal Sections ~~1223, 1227,~~ 1241.1, 1265, 1265.1, 1266, 1267, 1268, 1272.4, 1272.6, 1281, 1300.1, ~~1310,~~ 1324, and 1325 of, *and to repeal and add Sections 1223, 1227, and 1310 of*, the Business and Professions Code, to amend Section 9272 of the Food and Agricultural Code, to amend Sections 1206 and 1600.3 of the Health and Safety Code, and to amend Section 14043.27 of the Welfare and Institutions Code, relating to clinical laboratories.

LEGISLATIVE COUNSEL'S DIGEST

AB 1774, as amended, Bonilla. Clinical laboratories: licensure.

Existing federal law, the Clinical Laboratory Improvement Amendments of 1988 (CLIA) requires the federal Centers for Medicare and Medicaid Services to certify and regulate clinical laboratories that perform testing on humans. Complaints against individual laboratories are directed to the state.

Existing law provides for the licensure, registration, and regulation of clinical laboratories and various clinical laboratory personnel by the State Department of Public Health. Under existing law the department inspects clinical laboratories and assesses a fee for licensure of those facilities.

This bill would repeal the laws requiring a clinical laboratory to be licensed ~~and inspected~~ by the department, including the licensing ~~fee~~.

fee, and would recast the inspection role of the department to involve inspection and monitoring of specified issues for clinical laboratories that are not accredited by an accrediting organization approved under CLIA, investigation upon complaint, and sanctions, as provided. The bill would also make conforming changes.

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 654.1 of the Business and Professions  
2 Code is amended to read:  
3 654.1. (a) A person licensed under Chapter 4 (commencing  
4 with Section 1600) of this division or licensed under Chapter 5  
5 (commencing with Section 2000) of this division or licensed under  
6 any initiative act referred to in this division relating to osteopaths  
7 may not refer patients, clients, or customers to a clinical laboratory  
8 in which the licensee has a membership, proprietary interest, or  
9 coownership in any form, or has a profit-sharing arrangement,  
10 unless the licensee at the time of making the referral discloses in  
11 writing the interest to the patient, client, or customer. The written  
12 disclosure shall indicate that the patient may choose any clinical  
13 laboratory for purposes of having laboratory work or assignment  
14 performed.  
15 (b) This does shall not apply to persons who are members of a  
16 medical group that contracts to provide medical care to members  
17 of a group practice prepayment plan registered under the  
18 Knox-Keene Health Care Service Act of 1975 (Chapter 2.2  
19 (commencing with Section 1340) of Division 2 of the Health and  
20 Safety Code).  
21 (c) This does shall not apply to a referral to a clinical laboratory  
22 that is owned and operated by a health facility licensed pursuant  
23 to Chapter 2 (commencing with Section 1250) of Division 2 of  
24 the Health and Safety Code.  
25 (d) This section does not prohibit the acceptance of evaluation  
26 specimens for proficiency testing or referral of specimens or the  
27 assignment from one clinical laboratory to another clinical  
28 laboratory, either licensed or exempt under this chapter, providing  
29 the report indicates clearly the laboratory performing the test.

1 (e) “Proprietary interest” does not include ownership of a  
2 building where space is leased to a clinical laboratory at the  
3 prevailing rate under a straight lease arrangement.

4 (f) A violation of this section is a public offense and is  
5 punishable upon a first conviction by imprisonment in a county  
6 jail for not more than one year, or by imprisonment pursuant to  
7 subdivision (h) of Section 1170 of the Penal Code, or by a fine not  
8 exceeding ten thousand dollars (\$10,000), or by both that  
9 imprisonment and fine. A second or subsequent conviction shall  
10 be punishable by imprisonment pursuant to subdivision (h) of  
11 Section 1170 of the Penal Code.

12 SEC. 2. Section 655.5 of the Business and Professions Code  
13 is amended to read:

14 655.5. (a) It is unlawful for a person licensed under this  
15 division or under an initiative act referred to in this division, or a  
16 clinical laboratory, or a health facility when billing for a clinical  
17 laboratory of the facility, to charge, bill, or otherwise solicit  
18 payment from a patient, client, or customer for a clinical laboratory  
19 service not actually rendered by the person or clinical laboratory  
20 or under his, her or its direct supervision unless the patient, client,  
21 or customer is apprised at the first time of the charge, billing, or  
22 solicitation of the name, address, and charges of the clinical  
23 laboratory performing the service. The first written charge, bill,  
24 or other solicitation of payment shall separately set forth the name,  
25 address, and charges of the clinical laboratory concerned and shall  
26 clearly show whether or not the charge is included in the total of  
27 the account, bill, or charge. This subdivision is satisfied if the  
28 required disclosures are made to the third-party payer of the patient,  
29 client, or customer. If the patient is responsible for submitting the  
30 bill for the charges to the third-party payer, the bill provided to  
31 the patient for that purpose shall include the disclosures required  
32 by this section. This subdivision does not apply to a clinical  
33 laboratory of a health facility or a health facility when billing for  
34 a clinical laboratory of the facility nor to a person licensed under  
35 this division or under any initiative act referred to in this division  
36 if the standardized billing form used by the facility or person  
37 requires a summary entry for all clinical laboratory charges. For  
38 purposes of this subdivision, “health facility” has the same meaning  
39 as defined in Section 1250 of the Health and Safety Code.

1 (b) A clinical laboratory shall provide to each of its referring  
2 providers, upon request, a schedule of fees for services provided  
3 to patients of the referring provider. The schedule shall be provided  
4 within two working days after the clinical laboratory receives the  
5 request. For the purposes of this subdivision, a “referring provider”  
6 means a provider who has referred a patient to the clinical  
7 laboratory in the preceding six-month period. A clinical laboratory  
8 that provides a list of laboratory services to a referring provider  
9 or to a potential referring provider shall include a schedule of fees  
10 for the laboratory services listed.

11 (c) It is also unlawful for a person licensed under this division  
12 or under any initiative act referred to in this division to charge  
13 additional charges for a clinical laboratory service that is not  
14 actually rendered by the licensee to the patient and itemized in the  
15 charge, bill, or other solicitation of payment. This section shall not  
16 be construed to prohibit any of the following:

17 (1) An itemized charge for a service actually rendered to the  
18 patient by the licensee.

19 (2) A summary charge for services actually rendered to a patient  
20 by a health facility, as defined in Section 1250 of the Health and  
21 Safety Code, or by a person licensed under this division or under  
22 any initiative act referred to in this division if the standardized  
23 billing form used by the facility or person requires a summary  
24 entry for all clinical laboratory charges.

25 (d) As used in this section, the term “a person licensed under  
26 this division” includes a registered laboratory, as defined in Section  
27 1206, all wholly owned subsidiaries of the person, a parent  
28 company that wholly owns the person, and any subsidiaries wholly  
29 owned by the same parent that wholly owns the person. “Wholly  
30 owned” means ownership directly or through one or more  
31 subsidiaries. This section shall not apply to billings by a registered  
32 laboratory when the registered laboratory bills for services  
33 performed by a laboratory owned or operated by the registered  
34 laboratory.

35 (e) This section does not apply to a person or clinical laboratory  
36 who or which contracts directly with a health care service plan  
37 licensed pursuant to Section 1349 of the Health and Safety Code,  
38 if the services are to be provided to members of the plan on a  
39 prepaid basis and without additional charge or liability on account  
40 thereof.

1 (f) A violation of this section is a public offense and is  
2 punishable upon a first conviction by imprisonment in a county  
3 jail for not more than one year, or by imprisonment pursuant to  
4 subdivision (h) of Section 1170 of the Penal Code, or by a fine not  
5 exceeding ten thousand dollars (\$10,000), or by both that  
6 imprisonment and fine. A second or subsequent conviction is  
7 punishable by imprisonment pursuant to subdivision (h) of Section  
8 1170 of the Penal Code.

9 (g) (1) Notwithstanding subdivision (f), a violation of this  
10 section by a physician and surgeon for a first offense shall be  
11 subject to the exclusive remedy of reprimand by the Medical Board  
12 of California if the transaction that is the subject of the violation  
13 involves a charge for a clinical laboratory service that is less than  
14 the charge would have been if the clinical laboratory providing  
15 the service billed a patient, client, or customer directly for the  
16 clinical laboratory service, and if that clinical laboratory charge is  
17 less than the charge listed in the clinical laboratory's schedule of  
18 fees pursuant to subdivision (b).

19 (2) This subdivision does not permit a physician and surgeon  
20 to charge more than he or she was charged for the laboratory  
21 service by the clinical laboratory providing the service unless the  
22 additional charge is for service actually rendered by the physician  
23 and surgeon to the patient.

24 SEC. 3. Section 1206 of the Business and Professions Code is  
25 amended to read:

26 1206. (a) For the purposes of this chapter the following  
27 definitions are applicable:

28 (1) "Analyte" means the substance or constituent being  
29 measured, including, but not limited to, glucose, sodium, or  
30 theophylline, or any substance or property whose presence or  
31 absence, concentration, activity, intensity, or other characteristics  
32 are to be determined.

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

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

1 (4) “Blood gas analysis” means a clinical laboratory test or  
2 examination that deals with the uptake, transport, and  
3 metabolization of oxygen and carbon dioxide in the human body.

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

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

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

23 (8) “Clinical laboratory” means a place used, or an establishment  
24 or institution organized or operated, for the performance of clinical  
25 laboratory tests or examinations or the practical application of the  
26 clinical laboratory sciences. That application may include any  
27 means that applies the clinical laboratory sciences.

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

34 (10) “Direct and responsible supervision” means both of the  
35 following:

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

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

5 (11) “Licensed laboratory” means a clinical laboratory licensed  
6 pursuant to the federal Clinical Laboratory Improvement  
7 Amendments of 1988 (CLIA).

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

12 (13) “Physician office laboratory” means a clinical laboratory  
13 that is either: (A) owned and operated by a partnership or  
14 professional corporation that performs clinical laboratory tests or  
15 examinations only for patients of five or fewer physicians and  
16 surgeons or podiatrists who are shareholders, partners, or  
17 employees of the partnership or professional corporation that owns  
18 and operates the clinical laboratory; or (B) owned and operated  
19 by an individual licensed physician and surgeon or a podiatrist,  
20 and that performs clinical laboratory tests or examinations only  
21 for patients of the physician and surgeon or podiatrist who owns  
22 and operates the clinical laboratory.

23 (14) “Point-of-care laboratory testing device” means a portable  
24 laboratory testing instrument to which the following applies:

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

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

31 (C) It meets the following criteria:

32 (i) Performs clinical laboratory tests or examinations classified  
33 as waived or of moderate complexity under the federal Clinical  
34 Laboratory Improvement Amendments of 1988 (CLIA) (42 U.S.C.  
35 Sec. 263a).

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

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

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

5 (15) "Public health laboratory" means a laboratory that is  
6 operated by a city or county in conformity with Article 5  
7 (commencing with Section 101150) of Chapter 2 of Part 3 of  
8 Division 101 of the Health and Safety Code and the regulations  
9 adopted thereunder.

10 (16) "Registered laboratory" means a clinical laboratory that  
11 performs clinical laboratory tests or examinations subject to a  
12 certificate of waiver or a certificate of provider-performed  
13 microscopy under CLIA.

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

18 (18) "Subspecialty" for purposes of microbiology, means  
19 bacteriology, mycobacteriology, mycology, parasitology, virology,  
20 molecular biology, and serology for diagnosis of infectious  
21 diseases, or other subspecialty specified by regulation adopted by  
22 the department; for purposes of diagnostic immunology, means  
23 syphilis serology, general immunology, or other subspecialty  
24 specified by regulation adopted by the department; for purposes  
25 of chemistry, means routine chemistry, clinical microscopy,  
26 endocrinology, toxicology, or other subspecialty specified by  
27 regulation adopted by the department; for purposes of  
28 immunohematology, means ABO/Rh Type and Group, antibody  
29 detection for transfusion, antibody detection nontransfusion,  
30 antibody identification, compatibility, or other subspecialty  
31 specified by regulation adopted by the department; for pathology,  
32 means tissue pathology, oral pathology, diagnostic cytology, or  
33 other subspecialty specified by regulation adopted by the  
34 department; for purposes of genetics, means molecular biology  
35 related to the diagnosis of human genetic abnormalities,  
36 cytogenetics, or other subspecialty specified by regulation adopted  
37 by the department.

38 (b) This chapter does not restrict, limit, or prevent a person  
39 licensed to provide health care services under the laws of this state,  
40 including, but not limited to, licensed physicians and surgeons and

1 registered nurses, from practicing the profession or occupation for  
2 which he or she is licensed.

3 (c) This chapter does not authorize a person to perform or order  
4 health care services, or utilize the results of the clinical laboratory  
5 test or examination, unless the person is otherwise authorized to  
6 provide that care or utilize the results. The inclusion of a person  
7 in Section 1206.5 for purposes of performing a clinical laboratory  
8 test or examination shall not be interpreted to authorize a person,  
9 who is not otherwise authorized, to perform venipuncture, arterial  
10 puncture, or skin puncture.

11 SEC. 4. Section 1206.6 of the Business and Professions Code  
12 is amended to read:

13 1206.6. Subdivision (a) of Section 1206.5 does not apply to a  
14 pharmacist at a community pharmacy who, upon customer request,  
15 performs only blood glucose, hemoglobin A1c, or cholesterol tests  
16 that are classified as waived under CLIA and are approved by the  
17 federal Food and Drug Administration for sale to the public without  
18 a prescription in the form of an over-the-counter test kit, provided  
19 that all of the following requirements are satisfied:

20 (a) The pharmacy obtains a valid CLIA certificate of waiver  
21 and complies with all other requirements for the performance of  
22 waived clinical laboratory tests under applicable federal  
23 regulations. For purposes of CLIA, the person identified as  
24 responsible for directing and supervising testing oversight and  
25 decisionmaking shall be the pharmacist-in-charge, as defined in  
26 Section 4036.5.

27 (b) The pharmacy complies with this chapter.

28 (c) The tests are performed only by a pharmacist, as defined in  
29 Section 4036, in the course of performing routine patient  
30 assessment procedures in compliance with Section 4052.4.

31 SEC. 5. Section 1220 of the Business and Professions Code is  
32 amended to read:

33 1220. (a) (1) Each clinical laboratory shall maintain records,  
34 equipment, and facilities that are adequate and appropriate for the  
35 services rendered.

36 (2) (A) Except for tests or examinations classified as waived  
37 under CLIA, each clinical laboratory shall enroll, and demonstrate  
38 successful participation, as defined under CLIA, for each specialty  
39 and subspecialty in which it performs clinical laboratory tests or  
40 examinations, in a proficiency testing program approved by the

1 department or by CMS, to the same extent as required by CLIA  
2 in Subpart H (commencing with Section 493.801) of Title 42 of  
3 the Code of Federal Regulations. This requirement does not  
4 prohibit a clinical laboratory from performing clinical laboratory  
5 tests or examinations in a specialty or subspecialty for which there  
6 is no department or CMS approved proficiency testing program.

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

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

14 (c) The department shall conduct an investigation of complaints  
15 received concerning a clinical laboratory that may include an  
16 inspection of the laboratory.

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

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

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

26 (B) A quality control program that meets the requirements of  
27 CLIA in Subpart K (commencing with Section 493.1200) of Title  
28 42 of the Code of Federal Regulations as in effect on January 1,  
29 2015, and that may include the clinical laboratory's use of an  
30 Individualized Quality Control Plan, as incorporated into Appendix  
31 C of the State Operations Manual adopted by the federal Centers  
32 for Medicare and Medicaid Services (CMS).

33 (C) A comprehensive quality assurance program that meets the  
34 standards of CLIA in Subpart P (commencing with Section  
35 493.1701) of Title 42 of the Code of Federal Regulations.

36 SEC. 6. Section 1223 of the Business and Professions Code is  
37 repealed.

38 SEC. 7. *Section 1223 is added to the Business and Professions*  
39 *Code, to read:*

1 1223. *Clinical laboratories shall choose to be overseen by the*  
2 *department, pursuant to subdivision (a), or may seek certification*  
3 *of deemed status by an accrediting organization approved under*  
4 *CLIA, pursuant to subdivision (b). The accrediting organization*  
5 *may issue certificates of deemed status and may provide continued*  
6 *oversight to ensure compliance with state law.*

7 (a) *The department shall monitor, inspect, and investigate all*  
8 *clinical laboratories that are not accredited by an organization*  
9 *approved under CLIA for compliance with state standards that*  
10 *are in excess of federal standards.*

11 (b) (1) *A clinical laboratory that is accredited by an*  
12 *organization approved under CLIA shall be deemed to meet all*  
13 *state standards and shall not require monitoring, inspection, or*  
14 *investigation pursuant to subdivision (a), but may be subject to*  
15 *investigation by the department under other provisions of law.*

16 (2) *An accrediting organization shall provide the department*  
17 *with documentation of approval by the federal Centers for*  
18 *Medicare & Medicaid Services as an accrediting body under CLIA,*  
19 *a detailed comparison of the individual accreditation or approval*  
20 *requirements, with the comparable California condition-level*  
21 *requirements, including standards that are in excess of federal*  
22 *law, and a list of all of the clinical laboratories that operate in*  
23 *California, including the CLIA number and the expiration date of*  
24 *their accreditation, as applicable.*

25 (c) *The department may concentrate its resources on upholding*  
26 *personnel standards.*

27 ~~SEC. 7.~~

28 SEC. 8. *Section 1227 of the Business and Professions Code is*  
29 *repealed.*

30 SEC. 9. *Section 1227 is added to the Business and Professions*  
31 *Code, to read:*

32 1227. *The department shall post on its Internet Web site a*  
33 *comprehensive list of the differences between state and CLIA.*

34 ~~SEC. 8.~~

35 SEC. 10. *Section 1241.1 of the Business and Professions Code*  
36 *is repealed.*

37 ~~SEC. 9.~~

38 SEC. 11. *Section 1244 of the Business and Professions Code*  
39 *is amended to read:*

- 1 1244. This chapter does not restrict, limit, or prevent a program  
2 of nondiagnostic general health assessment provided that:
- 3 (1) The program complies with the requirements of CLIA for  
4 waived testing.
- 5 (2) The purpose of the program is to screen asymptomatic  
6 individuals for chronic health disorders and to refer individuals to  
7 licensed sources of care as indicated.
- 8 (3) The program does not test for human immunodeficiency  
9 virus or any reportable disease or condition identified in Section  
10 120130 of the Health and Safety Code or the regulations adopted  
11 under that section.
- 12 (4) The program utilizes only those devices that comply with  
13 all of the following:
- 14 (A) Meet all applicable state and federal performance standards  
15 pursuant to Section 111245 of the Health and Safety Code.
- 16 (B) Are not adulterated as specified in Article 2 (commencing  
17 with Section 111250) of Chapter 6 of Part 5 of Division 104 of  
18 the Health and Safety Code.
- 19 (C) Are not misbranded as specified in Article 3 (commencing  
20 with Section 111330) of Chapter 6 of Part 5 of Division 104 of  
21 the Health and Safety Code.
- 22 (D) Are not new devices unless they meet the requirements of  
23 Section 111550 of the Health and Safety Code.
- 24 (E) Are approved as waived tests and are used according to the  
25 manufacturer's instructions.
- 26 (5) Blood collection is performed by skin puncture only.
- 27 (6) Testing of a urine specimen is performed by the dipstick  
28 method only.
- 29 (7) Testing is performed on site and reported directly to the  
30 person requesting the test.
- 31 (8) The program maintains a supervisory committee consisting  
32 of, at a minimum, a licensed physician and surgeon and a clinical  
33 laboratory scientist licensed pursuant to this code.
- 34 (9) The supervisory committee for the program adopts written  
35 protocols that shall be followed in the program and that shall  
36 contain all of the following:
- 37 (A) Provision of written information to individuals to be  
38 assessed that shall include, but not be limited to, the following:
- 39 (i) The potential risks and benefits of assessment procedures to  
40 be performed in the program.

1 (ii) The limitations, including the nondiagnostic nature, of  
2 assessment examinations of biological specimens performed in  
3 the program.

4 (iii) Information regarding the risk factors or markers targeted  
5 by the program.

6 (iv) The need for followup with licensed sources of care for  
7 confirmation, diagnosis, and treatment as appropriate.

8 (B) Proper use of each device utilized in the program including  
9 the operation of analyzers, maintenance of equipment and supplies,  
10 and performance of quality control procedures including the  
11 determination of both accuracy and reproducibility of  
12 measurements in accordance with instructions provided by the  
13 manufacturer of the assessment device used.

14 (C) Proper procedures to be employed when collecting blood,  
15 if blood specimens are to be obtained.

16 (D) Proper procedures to be employed in handling and disposing  
17 of all biological specimens to be obtained and material  
18 contaminated by those biological specimens. These procedures  
19 shall comply with all county and city ordinances for medical waste  
20 management and blood-borne pathogen control that apply to the  
21 location where the program operates.

22 (E) Proper procedures to be employed in response to fainting,  
23 excessive bleeding, or other medical emergencies.

24 (F) Documentation that the testing personnel are following the  
25 instructions of the instrument's manufacturer, are trained in the  
26 performance of the test, and are competent to perform the testing  
27 without supervision.

28 (G) Reporting of assessment results to the individual being  
29 assessed.

30 (H) Referral and followup to licensed sources of care as  
31 indicated.

32 (10) (a) The written protocols adopted by the supervisory  
33 committee shall be maintained for at least one year following  
34 completion of the assessment program, during which period they  
35 shall be subject to review by department personnel and the local  
36 health officer or his or her designee, including the public health  
37 laboratory director.

38 (b) If skin puncture to obtain a blood specimen is to be  
39 performed in a program of nondiagnostic general health

1 assessment, the individual performing the skin puncture shall be  
2 authorized to perform skin puncture under this chapter.

3 (c) A program of nondiagnostic general health assessment that  
4 fails to meet the requirements set forth in subdivisions (a) and (b)  
5 shall not operate.

6 (d) For purposes of this section, “skin puncture” means the  
7 collection of a blood specimen by the finger prick method only  
8 and does not include venipuncture, arterial puncture, or any other  
9 procedure for obtaining a blood specimen.

10 (e) This chapter does not prohibit a licensed clinical laboratory  
11 from operating a program of nondiagnostic general health  
12 assessment provided that the clinical laboratory complies with the  
13 requirements of this section.

14 (f) A program for a health fair providing diagnostic or screening  
15 tests is not a nondiagnostic general health assessment program if  
16 all of the requirements of this chapter are met, and the laboratory  
17 performing the testing is licensed by federal law or is operating  
18 with a waiver for the applicable procedures. For a test that is not  
19 authorized for self-ordering pursuant to Section 1246.5 and that  
20 is not for a nondiagnostic general health assessment pursuant to  
21 this section, the clinical laboratory participating in the health fair  
22 shall assure that the test is ordered onsite only by a person licensed  
23 under this division who is authorized under his or her scope of  
24 practice to order the test or by a person authorized by that licensee.  
25 The results of a test performed at a health fair shall be provided  
26 to the test subject along with an explanation of the results.

27 ~~SEC. 10.~~

28 *SEC. 12.* Section 1246.5 of the Business and Professions Code  
29 is amended to read:

30 1246.5. (a) Notwithstanding any other law, a person may  
31 request, and a licensed clinical laboratory or public health  
32 laboratory may perform, the laboratory tests specified in this  
33 section. A registered clinical laboratory may perform the laboratory  
34 tests specified in this section if the test is subject to a certificate  
35 of waiver under CLIA. A program for nondiagnostic general health  
36 assessment that includes a laboratory test specified in this section  
37 shall comply with the provisions of Section 1244. The results from  
38 any test may be provided directly to the person requesting the test  
39 if the test is on or for his or her own body. These test results shall  
40 be provided in a manner that presents clear information and that

1 identifies results indicating the need for referral to a physician and  
2 surgeon.

3 (b) The tests that may be conducted pursuant to this section are:  
4 pregnancy, glucose level, cholesterol, occult blood, and any other  
5 test for which there is a test for a particular analyte approved by  
6 the federal Food and Drug Administration for sale to the public  
7 without a prescription in the form of an over-the-counter test kit.  
8 A test approved only as an over-the-counter collection device may  
9 not be conducted pursuant to this section.

10 ~~SEC. 11.~~

11 *SEC. 13.* Section 1265 of the Business and Professions Code  
12 is repealed.

13 ~~SEC. 12.~~

14 *SEC. 14.* Section 1265.1 of the Business and Professions Code  
15 is repealed.

16 ~~SEC. 13.~~

17 *SEC. 15.* Section 1266 of the Business and Professions Code  
18 is repealed.

19 ~~SEC. 14.~~

20 *SEC. 16.* Section 1267 of the Business and Professions Code  
21 is repealed.

22 ~~SEC. 15.~~

23 *SEC. 17.* Section 1268 of the Business and Professions Code  
24 is repealed.

25 ~~SEC. 16.~~

26 *SEC. 18.* Section 1271.1 of the Business and Professions Code  
27 is amended to read:

28 1271.1. (a) A clinical laboratory that provides cytology  
29 services shall, if the laboratory ceases operation, preserve records,  
30 reports, cytology slides, and cell blocks as prescribed in subdivision  
31 (g) of Section 1271 and Section 1274.

32 (b) A person injured as a result of the laboratory's abandonment  
33 of records may bring an action in a court of competent jurisdiction  
34 for the amount of damages suffered as a result. If the laboratory  
35 was a corporation or partnership that has been dissolved, the person  
36 injured may bring an action against that corporation's or  
37 partnership's principal officers of record at the time of the  
38 dissolution.

39 (c) For purposes of this section, the following definitions shall  
40 apply:

1 (1) “Abandonment of records” means violating subdivision (a)  
2 and thereby leaving patients and physicians and surgeons without  
3 access to information to which they are entitled pursuant to this  
4 chapter.

5 (2) “Principal officers” means:

6 (A) In the case of a partnership other than a limited partnership,  
7 any partner.

8 (B) In the case of a limited partnership, any general partner, as  
9 defined in Section 15904.02 of the Corporations Code.

10 (C) In the case of a corporation, the chairperson of the board,  
11 the chief executive officer, and the president of the corporation.

12 ~~SEC. 17.~~

13 *SEC. 19.* Section 1272 of the Business and Professions Code  
14 is amended to read:

15 1272. A clinical laboratory shall participate in a CLIA-approved  
16 proficiency testing program and demonstrate satisfactory  
17 performance in all of the laboratory specialities that include tests  
18 performed in the laboratory. Proficiency shall be tested in the  
19 following specialties: microbiology, serology, clinical chemistry,  
20 hematology, cytology, and immunohematology.

21 *SEC. 20. Section 1272.1 is added to the Business and*  
22 *Professions Code, to read:*

23 1272.1. (a) *If a clinical laboratory ceases operations, the*  
24 *laboratory owners, or delegated representatives of the owners,*  
25 *and the laboratory directors shall notify the department of this*  
26 *fact, in writing, within 30 calendar days from the date a clinical*  
27 *laboratory ceases operation. For purposes of this section, a*  
28 *laboratory ceases operations when it suspends the performance*  
29 *of all clinical laboratory tests or examinations for 30 calendar*  
30 *days at the location for which the clinical laboratory is licensed*  
31 *or registered.*

32 (b) (1) *Notwithstanding any other law, owners and laboratory*  
33 *directors of all clinical laboratories, including those laboratories*  
34 *that cease operations, shall preserve medical records and*  
35 *laboratory records, as defined in this section, for three years from*  
36 *the date of testing, examination, or purchase, unless a longer*  
37 *retention period is required by any other law, and shall maintain*  
38 *an ability to provide those records when requested by the*  
39 *department or any duly authorized representative of the*  
40 *department.*

1 (2) For purposes of this subdivision, “medical records” means  
2 the test requisition or test authorization, or the patient’s chart or  
3 medical record if used as the test requisition, the final and  
4 preliminary test or examination result, and the name of the person  
5 contacted if the laboratory test or examination result indicated an  
6 imminent life-threatening result or was of panic value.

7 (3) For purposes of this subdivision, “laboratory records”  
8 means records showing compliance with CLIA and this chapter  
9 during a laboratory’s operation that are actual or true copies,  
10 either photocopies or electronically reproducible copies, of records  
11 for patient test management, quality control, quality assurance,  
12 and all invoices documenting the purchase or lease of laboratory  
13 equipment and test kits, reagents, or media.

14 (4) Information contained in medical records and laboratory  
15 records shall be confidential, and shall be disclosed only to  
16 authorized persons in accordance with federal, state, and local  
17 laws.

18 (c) The department or any person injured as a result of a  
19 laboratory’s abandonment or failure to retain records pursuant  
20 to this section may bring an action in a court of proper jurisdiction  
21 for any reasonable amount of damages suffered as a result thereof.

22 ~~SEC. 18.~~

23 *SEC. 21.* Section 1272.4 of the Business and Professions Code  
24 is repealed.

25 ~~SEC. 19.~~

26 *SEC. 22.* Section 1272.6 of the Business and Professions Code  
27 is repealed.

28 ~~SEC. 20.~~

29 *SEC. 23.* Section 1281 of the Business and Professions Code  
30 is repealed.

31 ~~SEC. 21.~~

32 *SEC. 24.* Section 1300 of the Business and Professions Code  
33 is amended to read:

34 1300. The amount of application and license fees under this  
35 chapter shall be as follows:

36 (a) The application fee for a histocompatibility laboratory  
37 director’s, clinical laboratory bioanalyst’s, clinical chemist’s,  
38 clinical microbiologist’s, clinical laboratory toxicologist’s, clinical  
39 cytogeneticist’s, or clinical genetic molecular biologist’s license  
40 is sixty-three dollars (\$63).

1 (b) The annual renewal fee for a histocompatibility laboratory  
2 director’s, clinical laboratory bioanalyst’s, clinical chemist’s,  
3 clinical microbiologist’s, clinical laboratory toxicologist’s, clinical  
4 cytogeneticist’s, or clinical genetic molecular biologist’s license  
5 is sixty-three dollars (\$63).

6 (c) The application fee for a clinical laboratory scientist’s or  
7 limited clinical laboratory scientist’s license is thirty-eight dollars  
8 (\$38).

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

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

14 (f) The application fee for a trainee’s license is thirteen dollars  
15 (\$13).

16 (g) The annual renewal fee for a trainee’s license is eight dollars  
17 (\$8).

18 (h) The application fee for a duplicate license is five dollars  
19 (\$5).

20 (i) The personnel licensing delinquency fee is equal to the annual  
21 renewal fee.

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

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

29 (l) The department shall establish an application fee and a  
30 renewal fee for a medical laboratory technician license, the total  
31 fees collected not to exceed the costs of the department for the  
32 implementation and operation of the program licensing and  
33 regulating medical laboratory technicians pursuant to Section  
34 1260.3.

35 ~~SEC. 22.~~

36 *SEC. 25.* Section 1300.1 of the Business and Professions Code  
37 is repealed.

38 ~~SEC. 23.~~

39 *SEC. 26.* Section 1301 of the Business and Professions Code  
40 is amended to read:

1 1301. (a) The department shall give written notice to all  
2 persons licensed pursuant to Section 1260, 1260.1, 1261, 1261.5,  
3 1262, 1264, or 1270 at least 30 days in advance of the regular  
4 renewal date that a renewal fee has not been paid. In addition, the  
5 department shall give written notice to licensed clinical laboratory  
6 bioanalysts or doctoral degree specialists and clinical laboratory  
7 scientists or limited clinical laboratory scientists by registered or  
8 certified mail 90 days in advance of the expiration of the fifth year  
9 that a renewal fee has not been paid and, if not paid before the  
10 expiration of the fifth year of delinquency, the licensee may be  
11 subject to reexamination.

12 (b) If the renewal fee is not paid for five or more years, the  
13 department may require an examination before reinstating the  
14 license, except that an examination shall not be required as a  
15 condition for reinstatement if the original license was issued  
16 without an examination. An examination shall not be required for  
17 reinstatement if the license was forfeited solely by reason of  
18 nonpayment of the renewal fee if the nonpayment was for less than  
19 five years.

20 (c) If the license is not renewed within 60 days after its  
21 expiration, the licensee, as a condition precedent to renewal, shall  
22 pay the delinquency fee identified in subdivision (i) of Section  
23 1300, in addition to the renewal fee in effect on the last preceding  
24 regular renewal date. Payment of the delinquency fee is not  
25 necessary if, within 60 days of the license expiration date, the  
26 licensee files an application for inactive status.

27 ~~SEC. 24.~~

28 *SEC. 27.* Section 1310 of the Business and Professions Code  
29 is repealed.

30 *SEC. 28.* *Section 1310 is added to the Business and Professions*  
31 *Code, to read:*

32 *1310. (a) If the department determines that a clinical*  
33 *laboratory does not substantially meet the requirements of this*  
34 *chapter or federal law, the department may impose any of the*  
35 *following:*

36 *(1) Directed plans of correction, as defined under CLIA.*

37 *(2) Civil money penalties in an amount ranging from fifty dollars*  
38 *(\$50) to three thousand dollars (\$3,000) per day of noncompliance,*  
39 *or per violation, for a condition-level deficiency that does not pose*  
40 *immediate jeopardy, to an amount ranging from three thousand*

1 *fifty dollars (\$3,050) to ten thousand dollars (\$10,000) per day of*  
 2 *noncompliance, or per violation, for a condition-level deficiency*  
 3 *that poses immediate jeopardy, but only after notice and an*  
 4 *opportunity to respond in accordance with Section 100171 of the*  
 5 *Health and Safety Code, and consideration of facts enumerated*  
 6 *in CLIA in Section 493.1834 of Title 42 of the Code of Federal*  
 7 *Regulations.*

8 (3) *Civil money penalties in an amount ranging from fifty dollars*  
 9 *(\$50) to three thousand dollars (\$3,000) per day of noncompliance,*  
 10 *or per violation, for failure to comply with disease reporting*  
 11 *requirements, but only after notice and an opportunity to respond*  
 12 *in accordance with Section 100171 of the Health and Safety Code.*

13 (4) *Onsite monitoring, as defined under CLIA, and payment for*  
 14 *the costs of onsite monitoring.*

15 (5) *Any combination of the actions described in paragraphs (1)*  
 16 *to (4), inclusive.*

17 (b) *The department or its agents may enter and inspect a clinical*  
 18 *laboratory at any time to enforce state laws and regulations,*  
 19 *including, but not limited to, state standards that are more stringent*  
 20 *than federal standards.*

21 ~~SEC. 25.~~

22 ~~SEC. 29.~~ Section 1320 of the Business and Professions Code  
 23 is amended to read:

24 1320. The department may deny, suspend, or revoke a license  
 25 issued pursuant to this chapter for any of the following reasons:

26 (a) Conduct involving moral turpitude or dishonest reporting  
 27 of tests.

28 (b) Violation by the applicant or licensee of this chapter or a  
 29 rule or regulation adopted pursuant thereto.

30 (c) Aiding, abetting, or permitting the violation of this chapter,  
 31 the rules or regulations adopted pursuant to this chapter, or the  
 32 Medical Practice Act (Chapter 5 (commencing with Section 2000)  
 33 of Division 2).

34 (d) Permitting a licensed trainee to perform tests or procure  
 35 specimens unless under direct and responsible supervision.

36 (e) Violation of any provision of this code governing the practice  
 37 of medicine and surgery.

38 (f) Proof that an applicant or licensee has made false statements  
 39 in any material regard on the application for a license or renewal  
 40 issued pursuant to this chapter.

1 (g) Conduct inimical to the public health, morals, welfare, or  
2 safety of the people of the State of California in the provision of  
3 services for which a license is issued pursuant to this chapter.

4 (h) Proof that the applicant or licensee has used a degree or  
5 certificate as a means of qualifying for licensure that has been  
6 purchased or procured by barter or by any unlawful means or  
7 obtained from an institution that, at the time the degree, certificate,  
8 or title was obtained, was not recognized or accredited by the  
9 department of education of the state where the institution is or was  
10 located to give training in the field of study in which the degree,  
11 certificate, or title is claimed.

12 (i) Violation of any of the prenatal laws or regulations pertaining  
13 thereto in Chapter 2 (commencing with Section 120675) of Part  
14 3 of Division 105 of the Health and Safety Code and Article 1  
15 (commencing with Section 1125) of Group 4 of Subchapter 1 of  
16 Chapter 2 of Part 1 of Title 17 of the California Code of  
17 Regulations.

18 (j) Knowingly accepting an assignment for clinical laboratory  
19 tests or specimens from, and the rendering of a report thereon to,  
20 persons not authorized by law to submit those specimens or  
21 assignments.

22 (k) Rendering a report on clinical laboratory work actually  
23 performed in another clinical laboratory without designating clearly  
24 the name and address of the laboratory in which the test was  
25 performed.

26 (l) Conviction of a felony or misdemeanor involving moral  
27 turpitude under the laws of any state or of the United States arising  
28 out of or in connection with the practice of clinical laboratory  
29 technology. The record of conviction or a certified copy thereof  
30 shall be conclusive evidence of that conviction.

31 (m) Unprofessional conduct.

32 (n) The use of drugs or alcoholic beverages to the extent or in  
33 a manner as to be dangerous to a person licensed under this chapter,  
34 or any other person to the extent that use impairs the ability of the  
35 licensee to conduct, with safety to the public, the practice of clinical  
36 laboratory technology.

37 (o) Misrepresentation in obtaining a license.

38 (p) Performance of a clinical laboratory test or examination or  
39 other procedure that is not within the specialties or subspecialties,  
40 or category of laboratory procedures authorized by the license.

1 ~~SEC. 26.~~

2 *SEC. 30.* Section 1324 of the Business and Professions Code  
3 is repealed.

4 ~~SEC. 27.~~

5 *SEC. 31.* Section 1325 of the Business and Professions Code  
6 is repealed.

7 ~~SEC. 28.~~

8 *SEC. 32.* Section 9272 of the Food and Agricultural Code is  
9 amended to read:

10 9272. The provisions of this chapter shall not apply (1) to  
11 facilities primarily engaged in the collection, preparation, testing,  
12 processing, storage, or distribution of human blood or blood  
13 products, provided the facility is licensed pursuant to Chapter 4  
14 (commencing with Section 1600) of Division 2 of the Health and  
15 Safety Code and any biologic, as defined in Section 9203, produced  
16 by the facility is sold or distributed only to an establishment  
17 licensed by this chapter or (2) to clinical laboratories whose only  
18 biologics are autogenous bacterins prepared at the request of  
19 licensed veterinarians.

20 ~~SEC. 29.~~

21 *SEC. 33.* Section 1206 of the Health and Safety Code is  
22 amended to read:

23 1206. This chapter does not apply to the following:

24 (a) Except with respect to the option provided with regard to  
25 surgical clinics in paragraph (1) of subdivision (b) of Section 1204  
26 and, further, with respect to specialty clinics specified in paragraph  
27 (2) of subdivision (b) of Section 1204, a place or establishment  
28 owned or leased and operated as a clinic or office by one or more  
29 licensed health care practitioners and used as an office for the  
30 practice of their profession, within the scope of their license,  
31 regardless of the name used publicly to identify the place or  
32 establishment.

33 (b) A clinic directly conducted, maintained, or operated by the  
34 United States or by any of its departments, officers, or agencies,  
35 and any primary care clinic specified in subdivision (a) of Section  
36 1204 that is directly conducted, maintained, or operated by this  
37 state or by any of its political subdivisions or districts, or by any  
38 city. Nothing in this subdivision precludes the department from  
39 adopting regulations that utilize clinic licensing standards as  
40 eligibility criteria for participation in programs funded wholly or

1 partially under Title XVIII or XIX of the federal Social Security  
2 Act.

3 (c) (1) A clinic conducted, maintained, or operated by a  
4 federally recognized Indian tribe or tribal organization, as defined  
5 in Section 450 or 1603 of Title 25 of the United States Code, that  
6 is located on land recognized as tribal land by the federal  
7 government.

8 (2) A clinic conducted, maintained, or operated by a federally  
9 recognized Indian tribe or tribal organization, as defined in Section  
10 450 or 1603 of Title 25 of the United States Code, under a contract  
11 with the United States pursuant to the Indian Self-Determination  
12 and Education Assistance Act (Public Law 93-638), regardless of  
13 the location of the clinic, except that if the clinic chooses to apply  
14 to the State Department of Public Health for a state facility license,  
15 then the State Department of Public Health will retain authority  
16 to regulate that clinic as a primary care clinic as defined by  
17 subdivision (a) of Section 1204.

18 (d) Clinics conducted, operated, or maintained as outpatient  
19 departments of hospitals.

20 (e) A facility licensed as a health facility under Chapter 2  
21 (commencing with Section 1250).

22 (f) A freestanding clinical or pathological laboratory.

23 (g) A clinic operated by, or affiliated with, an institution of  
24 learning that teaches a recognized healing art and is approved by  
25 the state board or commission vested with responsibility for  
26 regulation of the practice of that healing art.

27 (h) A clinic that is operated by a primary care community or  
28 free clinic and that is operated on separate premises from the  
29 licensed clinic and is only open for limited services of no more  
30 than 30 hours a week. An intermittent clinic, as described in this  
31 subdivision, shall meet all other requirements of law, including  
32 administrative regulations and requirements, pertaining to fire and  
33 life safety.

34 (i) The offices of physicians in group practice who provide a  
35 preponderance of their services to members of a comprehensive  
36 group practice prepayment health care service plan subject to  
37 Chapter 2.2 (commencing with Section 1340).

38 (j) Student health centers operated by public institutions of  
39 higher education.

1 (k) Nonprofit speech and hearing centers, as defined in Section  
2 1201.5. A nonprofit speech and hearing clinic desiring an  
3 exemption under this subdivision shall apply to the director, who  
4 shall grant the exemption to any facility meeting the criteria of  
5 Section 1201.5. Notwithstanding the licensure exemption contained  
6 in this subdivision, a nonprofit speech and hearing center shall be  
7 deemed to be an organized outpatient clinic for purposes of  
8 qualifying for reimbursement as a rehabilitation center under the  
9 Medi-Cal Act (Chapter 7 (commencing with Section 14000) of  
10 Part 3 of Division 9 of the Welfare and Institutions Code).

11 (l) A clinic operated by a nonprofit corporation exempt from  
12 federal income taxation under paragraph (3) of subsection (c) of  
13 Section 501 of the Internal Revenue Code of 1954, as amended,  
14 or a statutory successor thereof, that conducts medical research  
15 and health education and provides health care to its patients through  
16 a group of 40 or more physicians and surgeons, who are  
17 independent contractors representing not less than 10  
18 board-certified specialties, and not less than two-thirds of whom  
19 practice on a full-time basis at the clinic.

20 (m) A clinic, limited to in vivo diagnostic services by magnetic  
21 resonance imaging functions or radiological services under the  
22 direct and immediate supervision of a physician and surgeon who  
23 is licensed to practice in California. This shall not be construed to  
24 permit cardiac catheterization or any treatment modality in these  
25 clinics.

26 (n) A clinic operated by an employer or jointly by two or more  
27 employers for their employees only, or by a group of employees,  
28 or jointly by employees and employers, without profit to the  
29 operators thereof or to any other person, for the prevention and  
30 treatment of accidental injuries to, and the care of the health of,  
31 the employees comprising the group.

32 (o) A community mental health center, as defined in Section  
33 5667 of the Welfare and Institutions Code.

34 (p) (1) A clinic operated by a nonprofit corporation exempt  
35 from federal income taxation under paragraph (3) of subsection  
36 (c) of Section 501 of the Internal Revenue Code of 1954, as  
37 amended, or a statutory successor thereof, as an entity organized  
38 and operated exclusively for scientific and charitable purposes and  
39 that satisfied all of the following requirements on or before January  
40 1, 2005:

- 1 (A) Commenced conducting medical research on or before  
2 January 1, 1982, and continues to conduct medical research.
- 3 (B) Conducted research in, among other areas, prostatic cancer,  
4 cardiovascular disease, electronic neural prosthetic devices,  
5 biological effects and medical uses of lasers, and human magnetic  
6 resonance imaging and spectroscopy.
- 7 (C) Sponsored publication of at least 200 medical research  
8 articles in peer-reviewed publications.
- 9 (D) Received grants and contracts from the National Institutes  
10 of Health.
- 11 (E) Held and licensed patents on medical technology.
- 12 (F) Received charitable contributions and bequests totaling at  
13 least five million dollars (\$5,000,000).
- 14 (G) Provides health care services to patients only:
- 15 (i) In conjunction with research being conducted on procedures  
16 or applications not approved or only partially approved for payment  
17 (I) under the Medicare program pursuant to Section 1359y(a)(1)(A)  
18 of Title 42 of the United States Code, or (II) by a health care service  
19 plan registered under Chapter 2.2 (commencing with Section 1340),  
20 or a disability insurer regulated under Chapter 1 (commencing  
21 with Section 10110) of Part 2 of Division 2 of the Insurance Code;  
22 provided that services may be provided by the clinic for an  
23 additional period of up to three years following the approvals, but  
24 only to the extent necessary to maintain clinical expertise in the  
25 procedure or application for purposes of actively providing training  
26 in the procedure or application for physicians and surgeons  
27 unrelated to the clinic.
- 28 (ii) Through physicians and surgeons who, in the aggregate,  
29 devote no more than 30 percent of their professional time for the  
30 entity operating the clinic, on an annual basis, to direct patient care  
31 activities for which charges for professional services are paid.
- 32 (H) Makes available to the public the general results of its  
33 research activities on at least an annual basis, subject to good faith  
34 protection of proprietary rights in its intellectual property.
- 35 (I) Is a freestanding clinic, whose operations under this  
36 subdivision are not conducted in conjunction with any affiliated  
37 or associated health clinic or facility defined under this division,  
38 except a clinic exempt from licensure under subdivision (m). For  
39 purposes of this subparagraph, a freestanding clinic is defined as  
40 “affiliated” only if it directly, or indirectly through one or more

1 intermediaries, controls, or is controlled by, or is under common  
2 control with, a clinic or health facility defined under this division,  
3 except a clinic exempt from licensure under subdivision (m). For  
4 purposes of this subparagraph, a freestanding clinic is defined as  
5 “associated” only if more than 20 percent of the directors or trustees  
6 of the clinic are also the directors or trustees of any individual  
7 clinic or health facility defined under this division, except a clinic  
8 exempt from licensure under subdivision (m). Any activity by a  
9 clinic under this subdivision in connection with an affiliated or  
10 associated entity shall fully comply with the requirements of this  
11 subdivision. This subparagraph shall not apply to agreements  
12 between a clinic and any entity for purposes of coordinating  
13 medical research.

14 (2) By January 1, 2007, and every five years thereafter, the  
15 Legislature shall receive a report from each clinic meeting the  
16 criteria of this subdivision and any other interested party  
17 concerning the operation of the clinic’s activities. The report shall  
18 include, but not be limited to, an evaluation of how the clinic  
19 impacted competition in the relevant health care market, and a  
20 detailed description of the clinic’s research results and the level  
21 of acceptance by the payer community of the procedures performed  
22 at the clinic. The report shall also include a description of  
23 procedures performed both in clinics governed by this subdivision  
24 and those performed in other settings. The cost of preparing the  
25 reports shall be borne by the clinics that are required to submit  
26 them to the Legislature pursuant to this paragraph.

27 ~~SEC. 30.~~

28 *SEC. 34.* Section 1600.3 of the Health and Safety Code is  
29 amended to read:

30 1600.3. “Blood bank depository” means a place other than a  
31 blood bank where human whole blood and human whole blood  
32 derivatives specified by regulation are stored and held for  
33 transfusion. Blood bank depositories shall be clinical laboratories,  
34 licensed in accordance with the provisions of federal law, or other  
35 places where services essentially equivalent are maintained, as  
36 determined by the department.

37 ~~SEC. 31.~~

38 *SEC. 35.* Section 14043.27 of the Welfare and Institutions  
39 Code is amended to read:

1 14043.27. (a) If an applicant or provider is granted provisional  
2 provider status or preferred provisional provider status pursuant  
3 to Section 14043.26 and, if at any time during the provisional  
4 provider status period or preferred provisional provider status  
5 period, the department conducts any announced or unannounced  
6 visits or any additional inspections or reviews pursuant to this  
7 chapter or Chapter 8 (commencing with Section 14200), or the  
8 regulations adopted thereunder, or pursuant to Section 100185.5  
9 of the Health and Safety Code, and discovers or otherwise  
10 determines the existence of any ground to deactivate the provider's  
11 number and business addresses or suspend the provider from the  
12 Medi-Cal program pursuant to this chapter or Chapter 8  
13 (commencing with Section 14200), or the regulations adopted  
14 thereunder, or pursuant to Section 100185.5 of the Health and  
15 Safety Code, or if any of the circumstances listed in subdivision  
16 (c) occur, the department shall terminate the provisional provider  
17 status or preferred provisional provider status of the provider,  
18 regardless of whether the period of time for which the provisional  
19 provider status or preferred provisional provider status was granted  
20 under Section 14043.26 has elapsed.

21 (b) Termination of provisional provider status or preferred  
22 provisional provider status shall include deactivation of the  
23 provider's number, including all business addresses used by the  
24 provider to obtain reimbursement from the Medi-Cal program and  
25 removal of the provider from enrollment in the Medi-Cal program,  
26 except where the termination is based upon a ground related solely  
27 to a specific location for which provisional provider status was  
28 granted. Termination of provisional provider status based upon  
29 grounds related solely to a specific location may include failure  
30 to have an established place of business, failure to possess the  
31 business or zoning permits or other approvals necessary to operate  
32 a business, or failure to possess the appropriate licenses, permits,  
33 or certificates necessary for the provider of service category or  
34 subcategory identified by the provider in its application package.  
35 Where the grounds relate solely to a specific location, the  
36 termination of provisional provider status shall include only  
37 deactivation of the specific locations that the grounds apply to and  
38 shall include removal of the provider from enrollment in the  
39 Medi-Cal program only if, after deactivation of the specific

1 locations, the provider does not have any business address that is  
2 not deactivated.

3 (c) The following circumstances are grounds for termination of  
4 provisional provider status or preferred provisional provider status:

5 (1) The provider, persons with an ownership or control interest  
6 in the provider, or persons who are directors, officers, or managing  
7 employees of the provider have been convicted of any felony, or  
8 convicted of any misdemeanor involving fraud or abuse in any  
9 government program, related to neglect or abuse of a patient in  
10 connection with the delivery of a health care item or service, or in  
11 connection with the interference with, or obstruction of, any  
12 investigation into health care related fraud or abuse, or have been  
13 found liable for fraud or abuse in any civil proceeding, or have  
14 entered into a settlement in lieu of conviction for fraud or abuse  
15 in any government program within 10 years of the date of the  
16 application package.

17 (2) There is a material discrepancy in the information provided  
18 to the department, or with the requirements to be enrolled, that is  
19 discovered after provisional provider status or preferred provisional  
20 provider status has been granted and that cannot be corrected  
21 because the discrepancy occurred in the past.

22 (3) The provider has provided material information that was  
23 false or misleading at the time it was provided.

24 (4) The provider failed to have an established place of business  
25 at the business address for which the application package was  
26 submitted at the time of any onsite inspection, announced or  
27 unannounced visit, or any additional inspection or review  
28 conducted pursuant to this article or a statute or regulation  
29 governing the Medi-Cal program, unless the practice of the  
30 provider's profession or delivery of services, goods, supplies, or  
31 merchandise is such that services, goods, supplies, or merchandise  
32 are rendered or delivered at locations other than the business  
33 address and this practice or delivery of services, goods, supplies,  
34 or merchandise has been disclosed in the application package  
35 approved by the department when the provisional provider status  
36 or preferred provisional provider status was granted.

37 (5) The provider meets the definition of a clinic under Section  
38 1200 of the Health and Safety Code, but is not licensed as a clinic  
39 pursuant to Chapter 1 (commencing with Section 1200) of Division  
40 2 of the Health and Safety Code and fails to meet the requirements

1 to qualify for at least one exemption pursuant to Section 1206 or  
2 1206.1 of the Health and Safety Code.

3 (6) The provider performs clinical laboratory tests or  
4 examinations, but it or its personnel do not meet CLIA, and the  
5 regulations adopted thereunder, do not possess valid CLIA  
6 certificates, or are not exempt pursuant to Section 1241 of the  
7 Business and Professions Code.

8 (7) The provider fails to possess either of the following:

9 (A) The appropriate licenses, permits, certificates, or other  
10 approvals needed to practice the profession or occupation, or  
11 provide the services, goods, supplies, or merchandise the provider  
12 identified in the application package approved by the department  
13 when the provisional provider status or preferred provisional  
14 provider status was granted and for the location for which the  
15 application was submitted.

16 (B) The business or zoning permits or other approvals necessary  
17 to operate a business at the location identified in its application  
18 package approved by the department when the provisional provider  
19 status or preferred provisional provider status was granted.

20 (8) The provider, or if the provider is a clinic, group, partnership,  
21 corporation, or other association, any officer, director, or  
22 shareholder with a 10 percent or greater interest in that  
23 organization, commits two or more violations of the federal or  
24 state statutes or regulations governing the Medi-Cal program, and  
25 the violations demonstrate a pattern or practice of fraud, abuse, or  
26 provision of unnecessary or substandard medical services.

27 (9) The provider commits any violation of a federal or state  
28 statute or regulation governing the Medi-Cal program or of a statute  
29 or regulation governing the provider's profession or occupation  
30 and the violation represents a threat of immediate jeopardy or  
31 significant harm to any Medi-Cal beneficiary or to the public  
32 welfare.

33 (10) The provider submits claims for payment that subject a  
34 provider to suspension under Section 14043.61.

35 (11) The provider submits claims for payment for services,  
36 goods, supplies, or merchandise rendered at a location other than  
37 the business address or addresses listed on the application for  
38 enrollment, unless the practice of the provider's profession or  
39 delivery of services, goods, supplies, or merchandise is such that  
40 services, goods, supplies, or merchandise are rendered or delivered

1 at locations other than the business address and this practice or  
2 delivery of services, goods, supplies, or merchandise has been  
3 disclosed in the application package approved by the department  
4 when the provisional provider status was granted.

5 (12) The provider has not paid its fine, or has a debt due and  
6 owing, including overpayments and penalty assessments, to any  
7 federal, state, or local government entity that relates to Medicare,  
8 medicaid, Medi-Cal, or any other federal or state health care  
9 program, and has not made satisfactory arrangements to fulfill the  
10 obligation or otherwise been excused by legal process from  
11 fulfilling the obligation.

12 (d) If, during a provisional provider status period or a preferred  
13 provisional provider status period, the department conducts any  
14 announced or unannounced visits or any additional inspections or  
15 reviews pursuant to this chapter or Chapter 8 (commencing with  
16 Section 14200), or the regulations adopted thereunder, and  
17 commences an investigation for fraud or abuse, or discovers or  
18 otherwise determines that the provider is under investigation for  
19 fraud or abuse by any other state, local, or federal government law  
20 enforcement agency, the provider shall be subject to termination  
21 of provisional provider status or preferred provisional provider  
22 status, regardless of whether the period of time for which the  
23 provisional provider status or preferred provisional provider status  
24 was granted under Section 14043.26 has elapsed.

25 (e) A provider whose provisional provider status or preferred  
26 provisional provider status has been terminated pursuant to this  
27 section may appeal the termination in accordance with Section  
28 14043.65.

29 (f) Any department-recovered fine or debt due and owing,  
30 including overpayments, that are subsequently determined to have  
31 been erroneously collected shall be promptly refunded to the  
32 provider, together with interest paid in accordance with subdivision  
33 (e) of Section 14171 and Section 14172.5.

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