

ASSEMBLY BILL

No. 1774

Introduced by Assembly Member Bonilla

February 3, 2016

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 repeal Sections 1223, 1227, 1241.1, 1265, 1265.1, 1266, 1267, 1268, 1272.4, 1272.6, 1281, 1300.1, 1310, 1324, and 1325 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 introduced, 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. 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) ~~Persons~~—A person licensed under Chapter 4
4 (commencing with Section 1600) of this division or licensed under
5 Chapter 5 (commencing with Section 2000) of this division or
6 licensed under any initiative act referred to in this division relating
7 to osteopaths may not refer patients, clients, or customers to ~~any~~
8 a clinical laboratory ~~licensed under Section 1265~~ in which the
9 licensee has ~~any~~ a membership, proprietary interest, or coownership
10 in any form, or has ~~any~~ a profit-sharing arrangement, unless the
11 licensee at the time of making ~~such~~ the referral discloses in writing
12 ~~such~~ the interest to the patient, client, or customer. The written
13 disclosure shall indicate that the patient may choose any clinical
14 laboratory for purposes of having ~~any~~ laboratory work or
15 assignment performed.
16 ~~This~~
17 (b) ~~This section does~~ shall not apply to persons who are members
18 of a medical group ~~which~~ that contracts to provide medical care
19 to members of a group practice prepayment plan registered under
20 the Knox-Keene Health Care Service Act of ~~1975~~, Chapter 1975
21 (Chapter 2.2 (commencing with Section 1340) of Division 2 of
22 the Health and Safety ~~Code~~: Code).
23 ~~This~~
24 (c) ~~This section does~~ shall not apply to ~~any~~ a referral to a clinical
25 laboratory ~~which~~ that is owned and operated by a health facility
26 licensed pursuant to Chapter 2 (commencing with Section 1250)
27 of Division 2 of the Health and Safety Code.
28 ~~This~~
29 (d) ~~This section does~~ not prohibit the acceptance of evaluation
30 specimens for proficiency testing or referral of specimens or ~~such~~
31 the assignment from one clinical laboratory to another clinical
32 laboratory, either licensed or exempt under this chapter, providing
33 the report indicates clearly the laboratory performing the test.
34 ~~“Proprietary~~

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 ~~A~~

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

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

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

1 subdivision, “health facility” has the same meaning as defined in
 2 Section 1250 of the Health and Safety Code.

3 (b) ~~Commencing July 1, 1994, a~~ A clinical laboratory shall
 4 provide to each of its referring providers, upon request, a schedule
 5 of fees for services provided to patients of the referring provider.
 6 The schedule shall be provided within two working days after the
 7 clinical laboratory receives the request. For the purposes of this
 8 subdivision, a “referring provider” means ~~any~~ a provider who has
 9 referred a patient to the clinical laboratory in the preceding
 10 six-month period. ~~Commencing July 1, 1994, a~~ A clinical laboratory
 11 that provides a list of laboratory services to a referring provider
 12 or to a potential referring provider shall include a schedule of fees
 13 for the laboratory services listed.

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

20 (1) ~~Any~~ An itemized charge for ~~any~~ a service actually rendered
 21 to the patient by the licensee.

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

28 (d) As used in this section, the term ~~“any~~ “a person licensed
 29 under this division” includes ~~a person licensed under paragraph~~
 30 ~~(1) of subdivision (a) of Section 1265, registered laboratory, as~~
 31 ~~defined in Section 1206,~~ all wholly owned subsidiaries of the
 32 person, a parent company that wholly owns the person, and any
 33 subsidiaries wholly owned by the same parent that wholly owns
 34 the person. “Wholly owned” means ownership directly or through
 35 one or more subsidiaries. This section shall not apply to billings
 36 by ~~a person licensed under paragraph (1) of subdivision (a) of~~
 37 ~~Section 1265 registered laboratory~~ when the ~~person licensed under~~
 38 ~~paragraph (1) of subdivision (a) of Section 1265 registered~~
 39 ~~laboratory~~ bills for services performed by ~~any~~ a laboratory owned

1 or operated by the ~~person licensed under paragraph (1) of~~
2 ~~subdivision (a) of Section 1265:~~ *registered laboratory.*

3 (e) This section ~~shall~~ *does* not apply to ~~any~~ a person or clinical
4 laboratory who or which contracts directly with a health care
5 service plan licensed pursuant to Section 1349 of the Health and
6 Safety Code, if the services are to be provided to members of the
7 plan on a prepaid basis and without additional charge or liability
8 on account thereof.

9 (f) A violation of this section is a public offense and is
10 punishable upon a first conviction by imprisonment in a county
11 jail for not more than one year, or by imprisonment pursuant to
12 subdivision (h) of Section 1170 of the Penal Code, or by a fine not
13 exceeding ten thousand dollars (\$10,000), or by both that
14 imprisonment and fine. A second or subsequent conviction is
15 punishable by imprisonment pursuant to subdivision (h) of Section
16 1170 of the Penal Code.

17 (g) (1) Notwithstanding subdivision (f), a violation of this
18 section by a physician and surgeon for a first offense shall be
19 subject to the exclusive remedy of reprimand by the Medical Board
20 of California if the transaction that is the subject of the violation
21 involves a charge for a clinical laboratory service that is less than
22 the charge would have been if the clinical laboratory providing
23 the service billed a patient, client, or customer directly for the
24 clinical laboratory service, and if that clinical laboratory charge is
25 less than the charge listed in the clinical laboratory's schedule of
26 fees pursuant to subdivision (b).

27 (2) ~~Nothing in this~~ *This* subdivision ~~shall be construed to~~ *does*
28 *not* permit a physician and surgeon to charge more than he or she
29 was charged for the laboratory service by the clinical laboratory
30 providing the service unless the additional charge is for service
31 actually rendered by the physician and surgeon to the patient.

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

34 1206. (a) For the purposes of this chapter the following
35 definitions are applicable:

36 (1) "Analyte" means the substance or constituent being ~~measured~~
37 *measured*, including, but not limited to, glucose, sodium, or
38 theophylline, or any substance or property whose presence or
39 absence, concentration, activity, intensity, or other characteristics
40 are to be determined.

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

3 (3) “Blood electrolyte analysis” means the measurement of
4 electrolytes in a blood specimen by means of ion selective
5 electrodes on instruments specifically designed and manufactured
6 for blood gas and acid-base analysis.

7 (4) “Blood gas analysis” means a clinical laboratory test or
8 examination that deals with the uptake, transport, and ~~metabolism~~
9 *metabolization* of oxygen and carbon dioxide in the human body.

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

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

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

29 (8) “Clinical laboratory” means ~~any~~ *a* place used, or ~~any~~ *an*
30 establishment or institution organized or operated, for the
31 performance of clinical laboratory tests or examinations or the
32 practical application of the clinical laboratory sciences. That
33 application may include any means that applies the clinical
34 laboratory sciences.

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

1 (10) “Direct and responsible supervision” means both of the
2 following:

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

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

11 (11) “Licensed laboratory” means a clinical laboratory licensed
12 ~~pursuant to paragraph (1) of subdivision (a) of Section 1265.~~
13 *pursuant to the federal Clinical Laboratory Improvement*
14 *Amendments of 1988 (CLIA).*

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

20 (13) “Physician office laboratory” means a clinical laboratory
21 that is ~~licensed or registered under Section 1265, and that is either:~~

22 (A) ~~a clinical laboratory that is owned and operated by a partnership~~
23 ~~or professional corporation that performs clinical laboratory tests~~
24 ~~or examinations only for patients of five or fewer physicians and~~
25 ~~surgeons or podiatrists who are shareholders, partners, or~~
26 ~~employees of the partnership or professional corporation that owns~~
27 ~~and operates the clinical laboratory; or (B) ~~a clinical laboratory~~~~
28 ~~that is owned and operated by an individual licensed physician~~
29 ~~and surgeon or a podiatrist, and that performs clinical laboratory~~
30 ~~tests or examinations only for patients of the physician and surgeon~~
31 ~~or podiatrist who owns and operates the clinical laboratory.~~

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

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

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

40 (C) It meets the following criteria:

- 1 (i) Performs clinical laboratory tests or examinations classified
2 as waived or of moderate complexity under the federal Clinical
3 Laboratory Improvement Amendments of 1988 (CLIA) (42 U.S.C.
4 Sec. 263a).
- 5 (ii) Performs clinical laboratory tests or examinations on
6 biological specimens that require no preparation after collection.
- 7 (iii) Provides clinical laboratory tests or examination results
8 without calculation or discretionary intervention by the testing
9 personnel.
- 10 (iv) Performs clinical laboratory tests or examinations without
11 the necessity for testing personnel to perform calibration or
12 maintenance, except resetting pursuant to the manufacturer's
13 instructions or basic cleaning.
- 14 (15) "Public health laboratory" means a laboratory that is
15 operated by a city or county in conformity with Article 5
16 (commencing with Section 101150) of Chapter 2 of Part 3 of
17 Division 101 of the Health and Safety Code and the regulations
18 adopted thereunder.
- 19 (16) "Registered laboratory" means a clinical laboratory
20 ~~registered pursuant to paragraph (2) of subdivision (a) of Section~~
21 ~~1265. that performs clinical laboratory tests or examinations~~
22 ~~subject to a certificate of waiver or a certificate of~~
23 ~~provider-performed microscopy under CLIA.~~
- 24 (17) "Specialty" means histocompatibility, microbiology,
25 diagnostic immunology, chemistry, hematology,
26 immunohematology, pathology, genetics, or other specialty
27 specified by regulation adopted by the department.
- 28 (18) "Subspecialty" for purposes of microbiology, means
29 bacteriology, mycobacteriology, mycology, parasitology, virology,
30 molecular biology, and serology for diagnosis of infectious
31 diseases, or other subspecialty specified by regulation adopted by
32 the department; for purposes of diagnostic immunology, means
33 syphilis serology, general immunology, or other subspecialty
34 specified by regulation adopted by the department; for purposes
35 of chemistry, means routine chemistry, clinical microscopy,
36 endocrinology, toxicology, or other subspecialty specified by
37 regulation adopted by the department; for purposes of
38 immunohematology, means ABO/Rh Type and Group, antibody
39 detection for transfusion, antibody detection nontransfusion,
40 antibody identification, compatibility, or other subspecialty

1 specified by regulation adopted by the department; for pathology,
2 means tissue pathology, oral pathology, diagnostic cytology, or
3 other subspecialty specified by regulation adopted by the
4 department; for purposes of genetics, means molecular biology
5 related to the diagnosis of human genetic abnormalities,
6 cytogenetics, or other subspecialty specified by regulation adopted
7 by the department.

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

13 (c) ~~Nothing in this~~ This chapter ~~shall~~ *does not* authorize ~~any~~ a
14 person to perform or order health care services, or utilize the results
15 of the clinical laboratory test or examination, unless the person is
16 otherwise authorized to provide that care or utilize the results. The
17 inclusion of a person in Section 1206.5 for purposes of performing
18 a clinical laboratory test or examination shall not be interpreted to
19 authorize a person, who is not otherwise authorized, to perform
20 venipuncture, arterial puncture, or skin puncture.

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

23 1206.6. Subdivision (a) of Section 1206.5 ~~shall~~ *does not* apply
24 to a pharmacist at a community pharmacy who, upon customer
25 request, performs only blood glucose, hemoglobin A1c, or
26 cholesterol tests that are classified as waived under CLIA and are
27 approved by the federal Food and Drug Administration for sale to
28 the public without a prescription in the form of an over-the-counter
29 test kit, provided that all of the following requirements are satisfied:

30 (a) The pharmacy obtains a valid CLIA certificate of waiver
31 and complies with all other requirements for the performance of
32 waived clinical laboratory tests under applicable federal
33 regulations. For purposes of CLIA, the person identified as
34 responsible for directing and supervising testing oversight and
35 decisionmaking shall be the pharmacist-in-charge, as defined in
36 Section 4036.5.

37 (b) ~~The pharmacy obtains a registration from the department~~
38 ~~pursuant to Section 1265 and~~ complies with this chapter.

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

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

6 1220. (a) (1) Each clinical laboratory shall maintain records,
7 equipment, and facilities that are adequate and appropriate for the
8 services rendered.

9 (2) (A) Except for tests or examinations classified as waived
10 under CLIA, each clinical laboratory shall enroll, and demonstrate
11 successful participation, as defined under CLIA, for each specialty
12 and subspecialty in which it performs clinical laboratory tests or
13 examinations, in a proficiency testing program approved by the
14 department or by ~~HCFA~~, *CMS*, to the same extent as required by
15 CLIA in Subpart H (commencing with Section 493.801) of Title
16 42 of the Code of Federal Regulations. This requirement ~~shall~~ *does*
17 ~~not be interpreted to~~ prohibit a clinical laboratory from performing
18 clinical laboratory tests or examinations in a specialty or
19 subspecialty for which there is no department or ~~HCFA~~ *CMS*
20 approved proficiency testing program.

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

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

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

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

35 ~~(3)~~

36 (c) The department shall conduct an investigation of complaints
37 received concerning ~~any a clinical laboratory, which laboratory~~
38 *that* may include an inspection of the laboratory.

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

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

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

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

13 (B) A quality control program that meets the requirements of
14 CLIA in Subpart K (commencing with Section 493.1200) of Title
15 42 of the Code of Federal Regulations as in effect on January 1,
16 2015, and that may include the clinical laboratory's use of the
17 following alternative quality control testing procedures recognized
18 *an Individualized Quality Control Plan, as incorporated into*
19 *Appendix C of the State Operations Manual adopted by the federal*
20 *Centers for Medicare and Medicaid Services (CMS): (CMS).*

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

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

26 (C) A comprehensive quality assurance program that meets the
27 standards of CLIA in Subpart P (commencing with Section
28 493.1701) of Title 42 of the Code of Federal Regulations.

29 SEC. 6. Section 1223 of the Business and Professions Code is
30 repealed.

31 ~~1223. (a) The Legislature finds and declares that it is the public~~
32 ~~policy of the state to ensure that California's laboratory standards,~~
33 ~~including its laboratory personnel standards, be sustained in order~~
34 ~~to provide accurate, reliable, and necessary test results. The~~
35 ~~Legislature further finds that inspections are the most effective~~
36 ~~means of furthering this policy. It is not the intent of the Legislature~~
37 ~~to reduce in any way the resources available to the department for~~
38 ~~inspections, but rather to provide the department with the greatest~~
39 ~~flexibility to concentrate its resources where they can be most~~
40 ~~effective. It is the intent of the Legislature to provide for an~~

1 inspection process that includes state-based inspection components
2 and that determines compliance with federal and state requirements
3 for clinical laboratories.

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

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

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

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

18 (i) ~~A detailed comparison of the individual accreditation or~~
19 ~~approval requirements, with the comparable condition-level~~
20 ~~requirements:~~

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

23 (I) ~~Frequency of inspections.~~

24 (II) ~~Copies of inspection forms.~~

25 (III) ~~Instructions and guidelines.~~

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

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

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

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

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

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

1 ~~(C) Conducts inspections of clinical laboratories in a manner~~
2 ~~that will determine compliance with federal standards and~~
3 ~~California laws to the extent that California laws provide greater~~
4 ~~protection to residents, or are more stringent than federal standards,~~
5 ~~as determined by the department. Notwithstanding any other~~
6 ~~provision of law, the department may, without taking regulatory~~
7 ~~action pursuant to Chapter 3.5 (commencing with Section 11340)~~
8 ~~of Part 1 of Division 3 of Title 2 of the Government Code,~~
9 ~~implement or interpret this section by means of an All Clinical~~
10 ~~Laboratories Letter (ACLL). The department shall post the ACLL~~
11 ~~on its Internet Web site so that any person may observe which~~
12 ~~California laws are more stringent than federal standards, and~~
13 ~~which accreditation bodies have been approved to conduct~~
14 ~~inspections. Public comment on the ACLL shall be accepted by~~
15 ~~the department for 30 days after posting and shall become final~~
16 ~~45 days after the posting. Comments received shall be considered~~
17 ~~by the department. Nothing in this subdivision is intended to~~
18 ~~change existing statutory or regulatory requirements governing~~
19 ~~the operation of clinical laboratories or their personnel.~~

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

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

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

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

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

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

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

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

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

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

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

34 ~~SEC. 7. Section 1227 of the Business and Professions Code is~~
35 ~~repealed.~~

36 ~~1227. Every person or clinical laboratory licensed or registered~~
37 ~~under this chapter shall report to the department, within 30 days~~
38 ~~thereof, any change of name or address.~~

39 ~~SEC. 8. Section 1241.1 of the Business and Professions Code~~
40 ~~is repealed.~~

1 ~~1241.1. (a) A primary care clinic, licensed pursuant to~~
2 ~~subdivision (a) of Section 1204 of the Health and Safety Code,~~
3 ~~that is operating within a network of primary care clinics, may be~~
4 ~~issued a license to operate a clinical laboratory pursuant to Section~~
5 ~~1265, which authorizes the conduct of clinical laboratory tests and~~
6 ~~examinations from its network of primary care clinics, if all of the~~
7 ~~following conditions are met:~~

8 ~~(1) The central laboratory's sole purpose is performing moderate~~
9 ~~or high complexity clinical laboratory tests and examinations, or~~
10 ~~both, for the patients of the clinics in the network.~~

11 ~~(2) Prior to performing any tests or examinations, the central~~
12 ~~laboratory obtains a certificate under the federal Clinical~~
13 ~~Laboratory Improvement Amendments of 1988 (42 U.S.C. 263a)~~
14 ~~(CLIA) and a state laboratory license for the appropriate complexity~~
15 ~~level of clinical laboratory testing pursuant to Section 1265.~~

16 ~~(b) For purposes of this section, "network of primary care~~
17 ~~clinics" means two or more primary care clinics operated by the~~
18 ~~same nonprofit corporation with the same board of directors and~~
19 ~~the same corporate officers, and operating under the same~~
20 ~~procedures and protocols.~~

21 SEC. 9. Section 1244 of the Business and Professions Code is
22 amended to read:

23 1244. ~~(a) Nothing in this~~ *This* chapter shall *does not* restrict,
24 limit, or prevent a program of nondiagnostic general health
25 assessment provided that:

26 ~~(1) The program meets the requirements of Section 1265 and~~
27 ~~complies with the requirements of CLIA for waived testing.~~

28 ~~(2) The purpose of the program is to screen asymptomatic~~
29 ~~individuals for chronic health disorders and to refer individuals to~~
30 ~~licensed sources of care as indicated.~~

31 ~~(3) The program does not test for human immunodeficiency~~
32 ~~virus or any reportable disease or condition identified in Section~~
33 ~~120130 of the Health and Safety Code or the regulations adopted~~
34 ~~under that section.~~

35 ~~(4) The program utilizes only those devices that comply with~~
36 ~~all of the following:~~

37 ~~(A) Meet all applicable state and federal performance standards~~
38 ~~pursuant to Section 111245 of the Health and Safety Code.~~

1 (B) Are not adulterated as specified in Article 2 (commencing
2 with Section 111250) of Chapter 6 of Part 5 of Division 104 of
3 the Health and Safety Code.

4 (C) Are not misbranded as specified in Article 3 (commencing
5 with Section 111330) of Chapter 6 of Part 5 of Division 104 of
6 the Health and Safety Code.

7 (D) Are not new devices unless they meet the requirements of
8 Section 111550 of the Health and Safety Code.

9 (E) Are approved as waived tests and are used according to the
10 manufacturer's instructions.

11 (5) Blood collection is performed by skin puncture only.

12 (6) Testing of a urine specimen is performed by the dipstick
13 method only.

14 (7) Testing is performed on site and reported directly to the
15 person requesting the test.

16 (8) The program maintains a supervisory committee consisting
17 of, at a minimum, a licensed physician and surgeon and a clinical
18 laboratory scientist licensed pursuant to this code.

19 (9) The supervisory committee for the program adopts written
20 protocols that shall be followed in the program and that shall
21 contain all of the following:

22 (A) Provision of written information to individuals to be
23 assessed that shall include, but not be limited to, the following:

24 (i) The potential risks and benefits of assessment procedures to
25 be performed in the program.

26 (ii) The limitations, including the nondiagnostic nature, of
27 assessment examinations of biological specimens performed in
28 the program.

29 (iii) Information regarding the risk factors or markers targeted
30 by the program.

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

33 (B) Proper use of each device utilized in the program including
34 the operation of analyzers, maintenance of equipment and supplies,
35 and performance of quality control procedures including the
36 determination of both accuracy and reproducibility of
37 measurements in accordance with instructions provided by the
38 manufacturer of the assessment device used.

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

1 (D) Proper procedures to be employed in handling and disposing
2 of all biological specimens to be obtained and material
3 contaminated by those biological specimens. These procedures
4 shall comply with all county and city ordinances for medical waste
5 management and blood-borne pathogen control that apply to the
6 location where the program operates.

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

9 (F) Documentation that the testing personnel are following the
10 instructions of the instrument's manufacturer, are trained in the
11 performance of the test, and are competent to perform the testing
12 without supervision.

13 (G) Reporting of assessment results to the individual being
14 assessed.

15 (H) Referral and followup to licensed sources of care as
16 indicated.

17 ~~The~~

18 (10) (a) *The* written protocols adopted by the supervisory
19 committee shall be maintained for at least one year following
20 completion of the assessment ~~program~~ *program*, during which
21 period they shall be subject to review by department personnel
22 and the local health officer or his or her designee, including the
23 public health laboratory director.

24 (b) If skin puncture to obtain a blood specimen is to be
25 performed in a program of nondiagnostic general health
26 assessment, the individual performing the skin puncture shall be
27 authorized to perform skin puncture under this chapter.

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

31 (d) For purposes of this section, "skin puncture" means the
32 collection of a blood specimen by the finger prick method only
33 and does not include venipuncture, arterial puncture, or any other
34 procedure for obtaining a blood specimen.

35 ~~Nothing in this~~ *This* chapter shall be interpreted as
36 ~~prohibiting~~ *does not prohibit* a licensed clinical laboratory from
37 operating a program of nondiagnostic general health assessment
38 provided that the clinical laboratory complies with the requirements
39 of this section.

1 (f) A program for a health fair providing diagnostic or screening
 2 tests is not a nondiagnostic general health assessment program if
 3 all of the requirements of this chapter are met, and the laboratory
 4 performing the testing is licensed ~~or registered under subdivision~~
 5 ~~(a) of Section 1265. by federal law or is operating with a waiver~~
 6 ~~for the applicable procedures.~~ For a test that is not authorized for
 7 self-ordering pursuant to Section 1246.5 and that is not for a
 8 nondiagnostic general health assessment pursuant to this section,
 9 the ~~licensed or registered~~ clinical laboratory participating in the
 10 health fair shall assure that the test is ordered ~~on-site~~ *onsite* only
 11 by a person licensed under this division who is authorized under
 12 his or her scope of practice to order the test or by a person
 13 authorized by that licensee. The results of a test performed at a
 14 health fair shall be provided to the test subject along with an
 15 explanation of the results.

16 SEC. 10. Section 1246.5 of the Business and Professions Code
 17 is amended to read:

18 1246.5. (a) Notwithstanding any other ~~provision of law, any~~
 19 ~~a~~ person may request, and ~~any a~~ licensed clinical laboratory or
 20 public health laboratory may perform, the laboratory tests specified
 21 in this section. A registered clinical laboratory may perform the
 22 laboratory tests specified in this section if the test is subject to a
 23 certificate of waiver under ~~CLIA and the laboratory has registered~~
 24 ~~with the department under paragraph (2) of subdivision (a) of~~
 25 ~~Section 1265. CLIA.~~ A program for nondiagnostic general health
 26 assessment that includes a laboratory test specified in this section
 27 shall comply with the provisions of Section 1244. The results from
 28 any test may be provided directly to the person requesting the test
 29 if the test is on or for his or her own body. These test results shall
 30 be provided in a manner that presents clear information and that
 31 identifies results indicating the need for referral to a physician and
 32 surgeon.

33 ~~The~~

34 (b) *The* tests that may be conducted pursuant to this section are:
 35 pregnancy, glucose level, cholesterol, occult blood, and any other
 36 test for which there is a test for a particular analyte approved by
 37 the federal Food and Drug Administration for sale to the public
 38 without a prescription in the form of an over-the-counter test kit.
 39 A test approved only as an over-the-counter collection device may
 40 not be conducted pursuant to this section.

1 SEC. 11. Section 1265 of the Business and Professions Code
2 is repealed.

3 ~~1265. (a) (1) A clinical laboratory performing clinical~~
4 ~~laboratory tests or examinations classified as of moderate or of~~
5 ~~high complexity under CLIA shall obtain a clinical laboratory~~
6 ~~license pursuant to this chapter. The department shall issue a~~
7 ~~clinical laboratory license to any person who has applied for the~~
8 ~~license on forms provided by the department and who is found to~~
9 ~~be in compliance with this chapter and the regulations pertaining~~
10 ~~thereto. No clinical laboratory license shall be issued by the~~
11 ~~department unless the clinical laboratory and its personnel meet~~
12 ~~the CLIA requirements for laboratories performing tests or~~
13 ~~examinations classified as of moderate or high complexity, or both.~~

14 ~~(2) A clinical laboratory performing clinical laboratory tests or~~
15 ~~examinations subject to a certificate of waiver or a certificate of~~
16 ~~provider-performed microseopy under CLIA, shall register with~~
17 ~~the department. The department shall issue a clinical laboratory~~
18 ~~registration to any person who has applied for the registration on~~
19 ~~forms provided by the department and is found to be in compliance~~
20 ~~with this chapter, the regulations pertaining thereto, and the CLIA~~
21 ~~requirements for either a certificate of waiver or a certificate of~~
22 ~~provider-performed microseopy.~~

23 ~~(b) An application for a clinical laboratory license or registration~~
24 ~~shall include the name or names of the owner or the owners, the~~
25 ~~name or names of the laboratory director or directors, the name~~
26 ~~and location of the laboratory, a list of the clinical laboratory tests~~
27 ~~or examinations performed by the laboratory by name and total~~
28 ~~number of test procedures and examinations performed annually~~
29 ~~(excluding tests the laboratory may run for quality control, quality~~
30 ~~assurance, or proficiency testing purposes). The application shall~~
31 ~~also include a list of the tests and the test kits, methodologies, and~~
32 ~~laboratory equipment used, and the qualifications (educational~~
33 ~~background, training, and experience) of the personnel directing~~
34 ~~and supervising the laboratory and performing the laboratory~~
35 ~~examinations and test procedures, and any other relevant~~
36 ~~information as may be required by the department. If the laboratory~~
37 ~~is performing tests subject to a provider-performed microseopy~~
38 ~~certificate, the name of the provider or providers performing those~~
39 ~~tests shall be included on the application. Application shall be~~
40 ~~made by the owners of the laboratory and the laboratory directors~~

1 prior to its opening. A license or registration to conduct a clinical
2 laboratory if the owners are not the laboratory directors shall be
3 issued jointly to the owners and the laboratory directors and the
4 license or registration shall include any information as may be
5 required by the department. The owners and laboratory directors
6 shall be severally and jointly responsible to the department for the
7 maintenance and conduct thereof or for any violations of this
8 chapter and regulations pertaining thereto.

9 (e) The department shall not issue a license or registration until
10 it is satisfied that the clinical laboratory will be operated within
11 the spirit and intent of this chapter, that the owners and laboratory
12 directors are each of good moral character, and that the granting
13 of the license will not be in conflict with the interests of public
14 health.

15 (d) A separate license or registration shall be obtained for each
16 laboratory location, with the following exceptions:

17 (1) Laboratories that are not at a fixed location, that is,
18 laboratories that move from one testing site to another, such as
19 mobile units providing laboratory testing, health screening fairs,
20 or other temporary testing locations, may apply for and obtain one
21 license or registration for the designated primary site or home base,
22 using the address of that primary site.

23 (2) Not-for-profit, or federal, state, or local government
24 laboratories that engage in limited (not more than a combination
25 of 15 moderately complex or waived tests, as defined under CLIA,
26 per license) public health testing may apply for and obtain a single
27 license or registration.

28 (3) Laboratories within a hospital that are located at contiguous
29 buildings on the same campus and under common direction, may
30 file a single application or multiple applications for a license or
31 registration of laboratory locations within the same campus or
32 street address.

33 (4) Locations within a single street and city address that are
34 under common ownership may apply for and obtain a single license
35 or registration or multiple licenses or registrations, at the discretion
36 of the owner or owners.

37 (e) (1) A license or registration shall be valid for one year unless
38 revoked or suspended. A clinical laboratory license or registration
39 shall be automatically revoked 30 days from a major change of
40 laboratory directorship or ownership. The clinical laboratory shall

1 be required to submit a completed application for a new clinical
2 laboratory license or registration within those 30 days or cease
3 engaging in clinical laboratory practice.

4 (2) ~~If a clinical laboratory intends to continue to engage in
5 clinical laboratory practice during the 30 days after a major change
6 in directorship occurs and before the laboratory license or
7 registration is automatically revoked, the laboratory owner may
8 appoint an interim director who meets the requirements of this
9 chapter and CLIA. The interim director shall be appointed within
10 five business days of the major change of the directorship. Written
11 notice shall be provided to the department of the appointment of
12 the laboratory director pursuant to this paragraph within five
13 business days of the appointment.~~

14 (f) ~~If the department does not within 60 days after the date of
15 receipt of the application issue a license or registration, it shall
16 state the grounds and reasons for its refusal in writing, serving a
17 copy upon the applicant by certified mail addressed to the applicant
18 at his or her last known address.~~

19 (g) ~~The department shall be notified in writing by the laboratory
20 owners or delegated representatives of the owners and the
21 laboratory directors of any change in ownership, directorship,
22 name, or location, including the addition or deletion of laboratory
23 owners or laboratory directors within 30 days. However, notice of
24 change in ownership shall be the responsibility of both the current
25 and new owners. Laboratory owners and directors to whom the
26 current license or registration is issued shall remain jointly and
27 severally responsible to the department for the operation,
28 maintenance, and conduct of the clinical laboratory and for any
29 violations of this chapter or the regulations adopted thereunder,
30 including any failure to provide the notifications required by this
31 subdivision, until proper notice is received by the department. In
32 addition, failure of the laboratory owners and directors to notify
33 the department within 30 days of any change in laboratory
34 directors, including any additions or deletions, shall result in the
35 automatic revocation of the clinical laboratory's license or
36 registration.~~

37 (h) ~~The withdrawal of an application for a license or registration
38 or for a renewal of a license, or registration, issuable under this
39 chapter, shall not, after the application has been filed with the
40 department, deprive the department of its authority to institute or~~

1 continue a proceeding against the applicant for denial of the license,
2 registration, or renewal upon any ground provided by law or to
3 enter an order denying the license, registration, or renewal upon
4 any such ground, unless the department consents in writing to the
5 withdrawal.

6 (i) ~~The suspension, expiration, or forfeiture by operation of law~~
7 ~~of a license or registration issued under this chapter, or its~~
8 ~~suspension, forfeiture, or cancellation by order of the department~~
9 ~~or by order of a court of law, or its surrender without the written~~
10 ~~consent of the department, shall not deprive the department of its~~
11 ~~authority to institute or continue an action against a license or~~
12 ~~registration issued under this chapter or against the laboratory~~
13 ~~owner or laboratory director upon any ground provided by law or~~
14 ~~to enter an order suspending or revoking the license or registration~~
15 ~~issued under this chapter.~~

16 (j) (1) ~~Whenever a clinical laboratory ceases operations, the~~
17 ~~laboratory owners, or delegated representatives of the owners, and~~
18 ~~the laboratory directors shall notify the department of this fact, in~~
19 ~~writing, within 30 calendar days from the date a clinical laboratory~~
20 ~~ceases operation. For purposes of this subdivision, a laboratory~~
21 ~~ceases operations when it suspends the performance of all clinical~~
22 ~~laboratory tests or examinations for 30 calendar days at the location~~
23 ~~for which the clinical laboratory is licensed or registered.~~

24 (2) (A) ~~Notwithstanding any other provision of law, owners~~
25 ~~and laboratory directors of all clinical laboratories, including those~~
26 ~~laboratories that cease operations, shall preserve medical records~~
27 ~~and laboratory records, as defined in this section, for three years~~
28 ~~from the date of testing, examination, or purchase, unless a longer~~
29 ~~retention period is required pursuant to any other provision of law,~~
30 ~~and shall maintain an ability to provide those records when~~
31 ~~requested by the department or any duly authorized representative~~
32 ~~of the department.~~

33 (B) ~~For purposes of this subdivision, “medical records” means~~
34 ~~the test requisition or test authorization, or the patient’s chart or~~
35 ~~medical record, if used as the test requisition, the final and~~
36 ~~preliminary test or examination result, and the name of the person~~
37 ~~contacted if the laboratory test or examination result indicated an~~
38 ~~imminent life-threatening result or was of panic value.~~

39 (C) ~~For purposes of this subdivision, “laboratory records” means~~
40 ~~records showing compliance with CLIA and this chapter during a~~

1 laboratory's operation that are actual or true copies, either
2 photocopies or electronically reproducible copies, of records for
3 patient test management, quality control, quality assurance, and
4 all invoices documenting the purchase or lease of laboratory
5 equipment and test kits, reagents, or media.

6 ~~(D) Information contained in medical records and laboratory~~
7 ~~records shall be confidential, and shall be disclosed only to~~
8 ~~authorized persons in accordance with federal, state, and local~~
9 ~~laws.~~

10 ~~(3) The department or any person injured as a result of a~~
11 ~~laboratory's abandonment or failure to retain records pursuant to~~
12 ~~this section may bring an action in a court of proper jurisdiction~~
13 ~~for any reasonable amount of damages suffered as a result thereof.~~

14 ~~(k) For purposes of this section, in the case of a pharmacy that~~
15 ~~applies for a registration pursuant to Section 1206.6, "laboratory~~
16 ~~director" means the pharmacist-in-charge identified pursuant to~~
17 ~~subdivision (a) of Section 1206.6.~~

18 SEC. 12. Section 1265.1 of the Business and Professions Code
19 is repealed.

20 ~~1265.1. (a) A primary care clinic that submits an application~~
21 ~~to the State Department of Public Health for clinic licensure~~
22 ~~pursuant to subdivision (a) of Section 1204 of the Health and Safety~~
23 ~~Code may submit prior to that submission, or concurrent therewith,~~
24 ~~an application for licensure or registration of a clinical laboratory~~
25 ~~to be operated by the clinic.~~

26 ~~(b) An application for licensure of a clinical laboratory submitted~~
27 ~~pursuant to this section shall be subject to all applicable laboratory~~
28 ~~licensing laws and regulations, including, but not limited to, any~~
29 ~~statutory or regulatory timelines and processes for review of a~~
30 ~~clinical laboratory application.~~

31 SEC. 13. Section 1266 of the Business and Professions Code
32 is repealed.

33 ~~1266. The clinical laboratory license and the license or current~~
34 ~~renewal permit of each person performing tests shall be~~
35 ~~conspicuously posted in the clinical laboratory.~~

36 SEC. 14. Section 1267 of the Business and Professions Code
37 is repealed.

38 ~~1267. Any denial, suspension, or revocation of a license under~~
39 ~~this chapter shall be conducted in compliance with Section 100171~~
40 ~~of the Health and Safety Code.~~

1 SEC. 15. Section 1268 of the Business and Professions Code
2 is repealed.

3 ~~1268. Upon filing application therefor, containing such~~
4 ~~information as the department may require, and the payment of~~
5 ~~the license fee, the department shall issue to any person duly~~
6 ~~licensed under this chapter a duplicate license for one previously~~
7 ~~issued or, where there has been a change of name, another license~~
8 ~~in lieu of one previously issued.~~

9 SEC. 16. Section 1271.1 of the Business and Professions Code
10 is amended to read:

11 ~~1271.1. (a) Clinical laboratories which are licensed pursuant~~
12 ~~to this chapter and provide~~ *A clinical laboratory that provides*
13 *cytology services shall, if the licensee laboratory ceases operation,*
14 *preserve records, reports, cytology slides, and cell blocks as*
15 *prescribed in subdivision (g) of Section 1271 and Section 1274.*

16 ~~(b) Any~~ *A person injured as a result of the licensee's*
17 *laboratory's abandonment of records may bring an action in any*
18 *a court of competent jurisdiction for the amount of any damages*
19 *suffered as a result. In the event the licensee* *If the laboratory was*
20 *a corporation or partnership which that has been dissolved, the*
21 *person injured may bring an action against that corporation's or*
22 *partnership's principal officers of record at the time of the*
23 *dissolution.*

24 (c) For purposes of this section, the following definitions shall
25 apply:

26 (1) "Abandonment of records" means violating subdivision (a)
27 and thereby leaving patients and physicians and surgeons without
28 access to information to which they are entitled pursuant to this
29 chapter.

30 (2) "Principal officers" means:

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

33 (B) In the case of a limited partnership, any general partner, as
34 defined in ~~subdivision (i) of Section 15611~~ *15904.02* of the
35 Corporations Code.

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

38 SEC. 17. Section 1272 of the Business and Professions Code
39 is amended to read:

1 1272. A clinical laboratory shall participate in a ~~state-approved~~
2 *CLIA-approved* proficiency testing program and demonstrate
3 satisfactory performance in all of the laboratory specialities that
4 include tests performed in the laboratory. Proficiency shall be
5 tested in the following specialties: microbiology, serology, clinical
6 chemistry, hematology, cytology, and immunohematology.

7 SEC. 18. Section 1272.4 of the Business and Professions Code
8 is repealed.

9 ~~1272.4. The department shall establish standards for the~~
10 ~~evaluation of cytologic slides, for reporting the adequacy of~~
11 ~~cytologic slides, for a cytotechnologist competency program, and~~
12 ~~for a proficiency testing program for clinical laboratories providing~~
13 ~~cytology services.~~

14 SEC. 19. Section 1272.6 of the Business and Professions Code
15 is repealed.

16 ~~1272.6. The department shall, on or before January 1, 1992,~~
17 ~~develop or adopt a proficiency testing program for laboratories~~
18 ~~providing cytology services which may be administered by the~~
19 ~~department or by a proficiency testing service or program approved~~
20 ~~by the department. The proficiency program established pursuant~~
21 ~~to this section shall include announced and unannounced onsite~~
22 ~~proficiency testing, with that testing to take place, to the extent~~
23 ~~practicable, under normal working conditions.~~

24 SEC. 20. Section 1281 of the Business and Professions Code
25 is repealed.

26 ~~1281. It is unlawful for any person to own, operate, maintain,~~
27 ~~direct, or engage in the business of operating a clinical laboratory,~~
28 ~~as defined in this chapter, unless he or she possesses a valid clinical~~
29 ~~laboratory license issued by the department. In the event a health~~
30 ~~facility does not perform clinical laboratory services, but provides~~
31 ~~laboratory services to its patients under an agreement with another~~
32 ~~person or entity that holds and is operating under a valid clinical~~
33 ~~laboratory license, the health facility shall not be required to obtain~~
34 ~~a clinical laboratory license.~~

35 SEC. 21. Section 1300 of the Business and Professions Code
36 is amended to read:

37 1300. The amount of ~~application, registration,~~ *application* and
38 license fees under this chapter shall be as follows:

39 (a) The application fee for a histocompatibility laboratory
40 director's, clinical laboratory bioanalyst's, clinical chemist's,

1 clinical microbiologist’s, clinical laboratory toxicologist’s, clinical
 2 cytogeneticist’s, or clinical genetic molecular biologist’s license
 3 is sixty-three dollars ~~(\$63) commencing on July 1, 1983. (\$63).~~

4 (b) The annual renewal fee for a histocompatibility laboratory
 5 director’s, clinical laboratory bioanalyst’s, clinical chemist’s,
 6 clinical microbiologist’s, clinical laboratory toxicologist’s, clinical
 7 cytogeneticist’s, or clinical genetic molecular biologist’s license
 8 is sixty-three dollars ~~(\$63) commencing on July 1, 1983. (\$63).~~

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

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

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

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

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

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

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

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

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

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

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

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

39 ~~(9) More than 1,000,000 tests: five thousand two hundred sixty~~
 40 ~~dollars (\$5,260) plus three hundred fifty dollars (\$350) for every~~

1 ~~500,000 tests over 1,000,000, up to a maximum of 15,000,000~~
2 ~~tests.~~

3 ~~(g) A clinical laboratory performing tests or examinations~~
4 ~~classified as of moderate or of high complexity under CLIA and~~
5 ~~a clinical laboratory with a certificate issued under subdivision (c)~~
6 ~~of Section 1223 shall pay an annual renewal fee based on the~~
7 ~~number of tests it performed in the preceding calendar year, as~~
8 ~~follows:~~

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

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

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

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

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

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

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

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

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

28 ~~(h)~~

29 ~~(f) The application fee for a trainee's license is thirteen dollars~~
30 ~~(\$13) commencing on July 1, 1983. (\$13).~~

31 ~~(i)~~

32 ~~(g) The annual renewal fee for a trainee's license is eight dollars~~
33 ~~(\$8) commencing on July 1, 1983. (\$8).~~

34 ~~(j)~~

35 ~~(h) The application fee for a duplicate license is five dollars~~
36 ~~(\$5) commencing on July 1, 1983. (\$5).~~

37 ~~(k)~~

38 ~~(i) The personnel licensing delinquency fee is equal to the annual~~
39 ~~renewal fee.~~

40 ~~(t)~~

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

4 ~~(m) A clinical laboratory subject to registration under paragraph
5 (2) of subdivision (a) of Section 1265 and performing only those
6 clinical laboratory tests or examinations considered waived under
7 CLIA shall pay an annual fee of one hundred dollars (\$100). A
8 clinical laboratory subject to registration under paragraph (2) of
9 subdivision (a) of Section 1265 and performing only
10 provider-performed microscopy, as defined under CLIA, shall pay
11 an annual fee of one hundred fifty dollars (\$150). A clinical
12 laboratory performing both waived and provider-performed
13 microscopy shall pay an annual registration fee of one hundred
14 fifty dollars (\$150).~~

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

22 ~~(o)~~

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

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

32 ~~(q)~~

33 (l) The department shall establish an application fee and a
34 renewal fee for a medical laboratory technician license, the total
35 fees collected not to exceed the costs of the department for the
36 implementation and operation of the program licensing and
37 regulating medical laboratory technicians pursuant to Section
38 1260.3.

39 ~~(r) The costs of the department to conduct any reinspections to
40 ensure compliance of a laboratory applying for initial licensure~~

1 shall be paid by the laboratory. This additional cost for each visit
2 shall be equal to the initial application fee and shall be paid by the
3 laboratory prior to issuance of a license. The department shall not
4 charge a reinspection fee if the reinspection is due to error or
5 omission on the part of the department.

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

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

15 SEC. 22. Section 1300.1 of the Business and Professions Code
16 is repealed.

17 ~~1300.1. The application and renewal fees for clinical laboratory~~
18 ~~licenses specified in Section 1300 shall be adjusted annually in~~
19 ~~the manner specified in Section 100450 of the Health and Safety~~
20 ~~Code. The adjustments shall be rounded off to the nearest whole~~
21 ~~dollar amount.~~

22 SEC. 23. Section 1301 of the Business and Professions Code
23 is amended to read:

24 1301. ~~(a) The annual renewal fee for a clinical laboratory~~
25 ~~license or registration set under this chapter shall be paid during~~
26 ~~the 30-day period before the expiration date of the license or~~
27 ~~registration. If the license or registration is not renewed before the~~
28 ~~expiration date, the licensee or registrant, as a condition precedent~~
29 ~~to renewal, shall pay a delinquency fee equal to 25 percent of the~~
30 ~~annual renewal fee for up to 60 days after the expiration date, in~~
31 ~~addition to the annual renewal fee in effect on the last preceding~~
32 ~~regular renewal date. Failure to pay the annual renewal fee in~~
33 ~~advance during the time the license or registration remains in force~~
34 ~~shall, ipso facto, work a forfeiture of the license or registration~~
35 ~~after a period of 60 days from the expiration date of the license or~~
36 ~~registration.~~

37 ~~(b) (1) (a)~~ The department shall give written notice to all
38 persons licensed pursuant to Section 1260, 1260.1, 1261, 1261.5,
39 1262, 1264, or 1270 *at least* 30 days in advance of the regular
40 renewal date that a renewal fee has not been paid. In addition, the

1 department shall give written notice to licensed clinical laboratory
2 bioanalysts or doctoral degree specialists and clinical laboratory
3 scientists or limited clinical laboratory scientists by registered or
4 certified mail 90 days in advance of the expiration of the fifth year
5 that a renewal fee has not been paid ~~and~~ *and*, if not paid before
6 the expiration of the fifth year of ~~delinquency~~ *delinquency*, the
7 licensee may be subject to reexamination.

8 (2)

9 (b) If the renewal fee is not paid for five or more years, the
10 department may require an examination before reinstating the
11 license, except that ~~no~~ *an* examination shall *not* be required as a
12 condition for reinstatement if the original license was issued
13 without an examination. ~~No~~ *An* examination shall *not* be required
14 for reinstatement if the license was forfeited solely by reason of
15 nonpayment of the renewal fee if the nonpayment was for less than
16 five years.

17 (3)

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

26 SEC. 24. Section 1310 of the Business and Professions Code
27 is repealed.

28 ~~1310. If the department determines that a laboratory that has~~
29 ~~been issued a license or registration under this chapter, except for~~
30 ~~a laboratory only performing tests or examinations classified as~~
31 ~~waived under CLIA, no longer substantially meets the requirements~~
32 ~~of this chapter or the regulations adopted thereunder, the~~
33 ~~department, in lieu of, or in addition to, revocation or suspension~~
34 ~~of the license or registration under Section 1320 or 1323, may~~
35 ~~impose any of the following:~~

36 ~~(a) Directed plans of correction, as defined under CLIA.~~

37 ~~(b) 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 in
6 CLIA in Section 493.1834 of Title 42 of the Code of Federal
7 Regulations.

8 (e) ~~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 a violation of subdivision (t) of Section 1320,~~
11 ~~for failure to comply with disease reporting requirements, but only~~
12 ~~after notice and an opportunity to respond in accordance with~~
13 ~~Section 100171 of the Health and Safety Code.~~

14 (d) ~~Onsite monitoring, as defined under CLIA, and payment for~~
15 ~~the costs of onsite monitoring.~~

16 (e) ~~Any combination of the actions described in subdivisions~~
17 ~~(a), (b), (c), and (d).~~

18 SEC. 25. Section 1320 of the Business and Professions Code
19 is amended to read:

20 1320. The department may deny, suspend, or revoke ~~any a~~
21 ~~license or registration issued under pursuant to~~ this chapter for
22 any of the following reasons:

23 (a) Conduct involving moral turpitude or dishonest reporting
24 of tests.

25 (b) Violation by the ~~applicant, licensee, or registrant~~ *applicant*
26 *or licensee* of this chapter or ~~any a~~ rule or regulation adopted
27 pursuant thereto.

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

32 (d) Permitting a licensed trainee to perform tests or procure
33 specimens unless under the direct and responsible ~~supervision of~~
34 ~~a person duly licensed under this chapter or physician and surgeon~~
35 ~~other than another licensed trainee.~~ *supervision.*

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

38 (f) Proof that an ~~applicant, licensee, or registrant~~ *applicant or*
39 *licensee* has made false statements in any material regard on the

1 application for a ~~license, registration,~~ *license* or renewal issued
2 ~~under pursuant to~~ this chapter.

3 (g) Conduct inimical to the public health, morals, welfare, or
4 safety of the people of the State of California in the ~~maintenance~~
5 ~~or operation of the premises or~~ *provision of* services for which a
6 ~~license or registration~~ is issued ~~under pursuant to~~ this chapter.

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

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

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

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

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

34 (m) Unprofessional conduct.

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

1 (o) Misrepresentation in obtaining a ~~license or registration.~~
2 ~~license.~~

3 (p) Performance of, or representation of the laboratory as entitled
4 to perform, of a clinical laboratory test or examination or other
5 procedure that is not within the specialties or subspecialties, or
6 category of laboratory procedures authorized by the ~~license or~~
7 ~~registration.~~ ~~license.~~

8 (q) ~~Refusal of a reasonable request of HCFA, a HCFA agent,~~
9 ~~the department, or any employee, agent, or contractor of the~~
10 ~~department, for permission to inspect, pursuant to this chapter, the~~
11 ~~laboratory and its operations and pertinent records during the hours~~
12 ~~the laboratory is in operation.~~

13 (r) ~~Failure to comply with reasonable requests of the department~~
14 ~~for any information, work, or materials that the department~~
15 ~~concludes is necessary to determine the laboratory's continued~~
16 ~~eligibility for its license or registration, or its continued compliance~~
17 ~~with this chapter or the regulations adopted under this chapter.~~

18 (s) ~~Failure to comply with a sanction imposed under Section~~
19 ~~1310.~~

20 (t) ~~Failure to comply with the disease reporting requirements~~
21 ~~adopted pursuant to Section 120130 of the Health and Safety Code.~~
22 ~~However, when a laboratory is not able to obtain complete~~
23 ~~information for a patient within the reporting timeframes, it shall~~
24 ~~document that it made a good faith effort to do so and it shall~~
25 ~~submit the report with the available information within the required~~
26 ~~reporting timeframes and, in that case, the laboratory shall not be~~
27 ~~subject to sanctions for failure to submit complete patient~~
28 ~~information.~~

29 SEC. 26. Section 1324 of the Business and Professions Code
30 is repealed.

31 ~~1324. Except for a person or entity whose license was revoked~~
32 ~~automatically under Section 1265, no person or entity who has~~
33 ~~owned or operated a clinical laboratory that had its license or~~
34 ~~registration revoked may, within two years of the revocation of~~
35 ~~the license or registration, own or operate a laboratory for which~~
36 ~~a license or registration has been issued under this chapter.~~

37 SEC. 27. Section 1325 of the Business and Professions Code
38 is repealed.

39 ~~1325. Notwithstanding Sections 1267 and 1322, the license or~~
40 ~~registration of a clinical laboratory that has been excluded from~~

1 participation under the Medicare program (Title XVIII of the Social
 2 Security Act (42 U.S.C. Sec. 1395 et seq.)), under the Medicaid
 3 Program (Title XIX of the Social Security Act (42 U.S.C. Sec.
 4 1396 et seq.)), or that had its certificate revoked under CLIA, shall
 5 be automatically suspended by the department for the period the
 6 laboratory is so excluded or has its certificate revoked.

7 SEC. 28. Section 9272 of the Food and Agricultural Code is
 8 amended to read:

9 9272. The provisions of this chapter shall not apply (1) to
 10 facilities primarily engaged in the collection, preparation, testing,
 11 processing, storage, or distribution of human blood or blood
 12 products, provided ~~such~~ the facility is licensed pursuant to ~~Section~~
 13 ~~1601 or 1602 Chapter 4 (commencing with Section 1600) of~~
 14 ~~Division 2 of the Health and Safety Code and any biologic biologic,~~
 15 as defined in Section ~~9203~~ 9203, produced by ~~such~~ the facility is
 16 sold or distributed only to an establishment licensed by this chapter
 17 or (2) to clinical laboratories ~~licensed pursuant to Chapter 3~~
 18 ~~(commencing with Section 1200) of Division 2 of the Business~~
 19 ~~and Professions Code~~ whose only biologics are autogenous
 20 bacterins prepared at the request of licensed veterinarians.

21 SEC. 29. 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, ~~any~~ 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) ~~Any~~ A clinic directly conducted, maintained, or operated by
 34 the 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 ~~state~~ department
 39 from 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) ~~Any~~ 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) ~~Any~~ A clinic conducted, maintained, or operated by a
9 federally recognized Indian tribe or tribal organization, as defined
10 in Section 450 or 1603 of Title 25 of the United States Code, under
11 a contract with the United States pursuant to the Indian
12 Self-Determination and Education Assistance Act (Public Law
13 93-638), regardless of the location of the clinic, except that if the
14 clinic chooses to apply to the State Department of Public Health
15 for a state facility license, then the State Department of Public
16 Health will retain authority to regulate that clinic as a primary care
17 clinic as defined by subdivision (a) of Section 1204.

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

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

22 (f) ~~Any~~ A freestanding clinical or pathological ~~laboratory~~
23 licensed under Chapter 3 (commencing with Section 1200) of
24 Division 2 of the Business and Professions Code. *laboratory.*

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

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

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

1 (j) Student health centers operated by public institutions of
2 higher education.

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

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

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

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

35 (o) A community mental health center, as defined in Section
36 5667 of the Welfare and Institutions Code.

37 (p) (1) A clinic operated by a nonprofit corporation exempt
38 from federal income taxation under paragraph (3) of subsection
39 (c) of Section 501 of the Internal Revenue Code of 1954, as
40 amended, or a statutory successor thereof, as an entity organized

1 and operated exclusively for scientific and charitable purposes and
2 that satisfied all of the following requirements on or before January
3 1, 2005:

4 (A) Commenced conducting medical research on or before
5 January 1, 1982, and continues to conduct medical research.

6 (B) Conducted research in, among other areas, prostatic cancer,
7 cardiovascular disease, electronic neural prosthetic devices,
8 biological effects and medical uses of lasers, and human magnetic
9 resonance imaging and spectroscopy.

10 (C) Sponsored publication of at least 200 medical research
11 articles in peer-reviewed publications.

12 (D) Received grants and contracts from the National Institutes
13 of Health.

14 (E) Held and licensed patents on medical technology.

15 (F) Received charitable contributions and bequests totaling at
16 least five million dollars (\$5,000,000).

17 (G) Provides health care services to patients only:

18 (i) In conjunction with research being conducted on procedures
19 or applications not approved or only partially approved for payment
20 (I) under the Medicare program pursuant to Section 1359y(a)(1)(A)
21 of Title 42 of the United States Code, or (II) by a health care service
22 plan registered under Chapter 2.2 (commencing with Section 1340),
23 or a disability insurer regulated under Chapter 1 (commencing
24 with Section 10110) of Part 2 of Division 2 of the Insurance Code;
25 provided that services may be provided by the clinic for an
26 additional period of up to three years following the approvals, but
27 only to the extent necessary to maintain clinical expertise in the
28 procedure or application for purposes of actively providing training
29 in the procedure or application for physicians and surgeons
30 unrelated to the clinic.

31 (ii) Through physicians and surgeons who, in the aggregate,
32 devote no more than 30 percent of their professional time for the
33 entity operating the clinic, on an annual basis, to direct patient care
34 activities for which charges for professional services are paid.

35 (H) Makes available to the public the general results of its
36 research activities on at least an annual basis, subject to good faith
37 protection of proprietary rights in its intellectual property.

38 (I) Is a freestanding clinic, whose operations under this
39 subdivision are not conducted in conjunction with any affiliated
40 or associated health clinic or facility defined under this division,

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

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

30 SEC. 30. Section 1600.3 of the Health and Safety Code is
31 amended to read:

32 1600.3. “Blood bank depository” means ~~any~~ a place other than
33 a blood bank where human whole blood and human whole blood
34 derivatives specified by regulation are stored and held for
35 transfusion. ~~Such blood~~ *Blood* bank depositories shall be clinical
36 laboratories, licensed in accordance with the provisions of ~~Chapter~~
37 ~~3 (commencing with Section 1200), Division 2 of the Business~~
38 ~~and Professions Code, federal law, or such~~ other places where
39 services essentially equivalent are maintained, as determined by
40 the department.

1 SEC. 31. Section 14043.27 of the Welfare and Institutions
2 Code is amended to read:

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

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

1 Medi-Cal program only if, after deactivation of the specific
2 locations, the provider does not have any business address that is
3 not deactivated.

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

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

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

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

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

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

1 2 of the Health and Safety Code and fails to meet the requirements
2 to qualify for at least one exemption pursuant to Section 1206 or
3 1206.1 of the Health and Safety Code.

4 (6) The provider performs clinical laboratory tests or
5 examinations, but it or its personnel do not meet CLIA, and the
6 regulations adopted ~~thereunder, and the state clinical laboratory~~
7 ~~law, thereunder,~~ do not possess valid CLIA certificates and clinical
8 laboratory registrations or licenses pursuant to Chapter 3
9 (commencing with Section 1200) of Division 2 of the Business
10 and Professions Code, *certificates*, or are not exempt from licensure
11 as a clinical laboratory under *pursuant to* Section 1241 of the
12 Business and Professions Code.

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

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

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

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

32 (9) The provider commits any violation of a federal or state
33 statute or regulation governing the Medi-Cal program or of a statute
34 or regulation governing the provider's profession or occupation
35 and the violation represents a threat of immediate jeopardy or
36 significant harm to any Medi-Cal beneficiary or to the public
37 welfare.

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

1 (11) The provider submits claims for payment for services,
2 goods, supplies, or merchandise rendered at a location other than
3 the business address or addresses listed on the application for
4 enrollment, unless the practice of the provider's profession or
5 delivery of services, goods, supplies, or merchandise is such that
6 services, goods, supplies, or merchandise are rendered or delivered
7 at locations other than the business address and this practice or
8 delivery of services, goods, supplies, or merchandise has been
9 disclosed in the application package approved by the department
10 when the provisional provider status was granted.

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

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

31 (e) A provider whose provisional provider status or preferred
32 provisional provider status has been terminated pursuant to this
33 section may appeal the termination in accordance with Section
34 14043.65.

35 (f) Any department-recovered fine or debt due and owing,
36 including overpayments, that are subsequently determined to have
37 been erroneously collected shall be promptly refunded to the

- 1 provider, together with interest paid in accordance with subdivision
- 2 (e) of Section 14171 and Section 14172.5.

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