Senate Bill No. 1267

CHAPTER 473

An act to amend Sections 1203, 1204, 1205, 1206, 1207, 1210, 1261, 1261.5, 1264, and 1300 of the Business and Professions Code, relating to clinical laboratories.

[Approved by Governor September 22, 2022. Filed with Secretary of State September 22, 2022.]

LEGISLATIVE COUNSEL'S DIGEST

SB 1267, Pan. Clinical laboratories.

Existing law provides for the licensure, registration, and regulation of clinical laboratories and various clinical laboratory personnel by the State Department of Public Health. Existing law specifies what duties the various clinical laboratory personnel can perform. A violation of these provisions is a crime.

This bill would add geneticists and reproductive biologists to the types of clinical laboratory personnel that are licensed and regulated by the department and would define their subspecialities and duties. By creating a new crime, this bill would impose a state-mandated local program.

This bill would incorporate additional changes to Sections 1206 and 1210 of the Business and Professions Code proposed by AB 1328 and AB 2107, respectively, to be operative only if this bill and AB 1328 or AB 2107 are enacted and this bill is enacted last.

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

This bill would provide that no reimbursement is required by this act for a specified reason.

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

SECTION 1. Section 1203 of the Business and Professions Code is amended to read:

1203. As used in this chapter, "clinical laboratory bioanalyst" or "bioanalyst" means a person licensed under Section 1260 to engage in clinical laboratory practice and direction of a clinical laboratory.

(a) A person licensed as a clinical laboratory bioanalyst or bioanalyst and qualified under CLIA, who is not the CLIA laboratory director, may perform clinical laboratory tests or examinations classified as of high complexity under CLIA and the duties and responsibilities of a laboratory director in the specialties of histocompatibility, microbiology, diagnostic

immunology, chemistry, hematology, immunohematology, genetics, reproductive biology, or other specialty or subspecialty specified in regulations adopted by the department.

(b) A person licensed as a clinical laboratory bioanalyst or bioanalyst and qualified under CLIA may perform the duties and responsibilities of a CLIA laboratory director, technical consultant, clinical consultant, technical supervisor, and general supervisor, as specified under CLIA, in the specialties of histocompatibility, microbiology, diagnostic immunology, chemistry, hematology, immunohematology, genetics, reproductive biology, or other specialty or subspecialty specified in regulations adopted by the department.

(c) A person licensed as a clinical laboratory bioanalyst or bioanalyst may perform any clinical laboratory test or examination classified as waived or of moderate complexity under CLIA.

SEC. 2. Section 1204 of the Business and Professions Code is amended to read:

1204. As used in this chapter, "clinical laboratory scientist" means a person, other than a licensed clinical laboratory bioanalyst or trainee, who is licensed under Sections 1261 and 1262 to engage in clinical laboratory practice under the overall operation and administration of a laboratory director, unless serving as a director of a waived laboratory as provided in Section 1209. A person licensed as a clinical laboratory scientist and qualified under CLIA may perform clinical laboratory tests or examinations classified as of high complexity under CLIA and the duties and responsibilities of a waived laboratory director, as specified under CLIA, technical consultant, clinical consultant, technical supervisor, and general supervisor, as specified under CLIA, in the specialties of histocompatibility, microbiology, diagnostic immunology, chemistry, hematology, immunohematology, reproductive biology, genetics, or other specialty or subspecialty specified by regulation adopted by the department. A person licensed as a "clinical laboratory scientist" may perform any clinical laboratory test or examination classified as waived or of moderate complexity under CLIA.

SEC. 3. Section 1205 of the Business and Professions Code is amended to read:

1205. As used in this chapter, "trainee" means a person licensed under this chapter for the purpose of receiving comprehensive practical experience and instruction in clinical laboratory procedures in one of the sciences or in general clinical laboratory science under the direct and responsible supervision of a person authorized to direct a laboratory under the provisions of this chapter, clinical laboratory scientist, clinical chemist scientist, clinical microbiologist scientist, clinical toxicologist scientist, clinical immunohematologist scientist, clinical genetic molecular biologist scientist, clinical cytogeneticist scientist, clinical histocompatibility scientist, clinical laboratory geneticist scientist, clinical reproductive biologist scientist, or other equivalent licensee in the science or specialty or subspecialty for which the person is licensed in a clinical laboratory certified for this purpose by the department under this chapter.

SEC. 4. Section 1206 of the Business and Professions Code is amended to read:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(C) It meets the following criteria:

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

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

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

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

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

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

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

(18) "Subspecialty" means all of the following:

(A) For purposes of microbiology, means bacteriology, mycobacteriology, mycology, parasitology, virology, molecular biology, and serology for diagnosis of infectious diseases, or other subspecialty specified by regulation adopted by the department.

(B) For purposes of diagnostic immunology, means syphilis serology, general immunology, or other subspecialty specified by regulation adopted by the department.

(C) For purposes of chemistry, means routine chemistry, clinical microscopy, endocrinology, toxicology, or other subspecialty specified by regulation adopted by the department.

(D) For purposes of immunohematology, means ABO/Rh Type and Group, antibody detection for transfusion, antibody detection nontransfusion, antibody identification, compatibility, or other subspecialty specified by regulation adopted by the department.

(E) For pathology, means tissue pathology, oral pathology, diagnostic cytology, or other subspecialty specified by regulation adopted by the department.

(F) For purposes of genetics, means molecular biology related to the diagnosis of human genetic abnormalities, cytogenetics, biochemical genetics, laboratory genetics, or other subspecialty specified by regulation adopted by the department.

(G) For purposes of reproductive biology, means andrology and embryology, including diagnostic testing for management of primary and secondary infertility, fertility assessment, and fertility preservation, as well as the evaluation and assessment of gametes and embryos and their associated fluids and tissues, or other subspecialty specified by regulation adopted by the department. Reproductive biology does not include the qualitative assessment of sperm in preparation for intrauterine insemination.

(b) This chapter does not restrict, limit, or prevent a person licensed to provide health care services under the laws of this state, including, but not limited to, licensed physicians and surgeons and registered nurses, from practicing the profession or occupation for which the person is licensed.

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

SEC. 4.5. Section 1206 of the Business and Professions Code is amended to read:

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

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

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

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

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

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

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

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

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

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

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

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

(B) Personal review by the physician and surgeon or the licensed person of all results of clinical laboratory testing or examination performed by the

trainee for accuracy, reliability, and validity before the results are reported from the laboratory.

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

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

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

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

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

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

(C) It meets the following criteria:

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

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

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

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

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

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

(17) "Specialty" means histocompatibility, microbiology, diagnostic immunology, chemistry, hematology, immunohematology, pathology,

genetics, reproductive biology, or other specialty specified by regulation adopted by the department.

(18) "Subspecialty" means all of the following:

(A) For purposes of microbiology, means bacteriology, mycobacteriology, mycology, parasitology, virology, molecular biology, and serology for diagnosis of infectious diseases, or other subspecialty specified by regulation adopted by the department.

(B) For purposes of diagnostic immunology, means syphilis serology, general immunology, or other subspecialty specified by regulation adopted by the department.

(C) For purposes of chemistry, means routine chemistry, clinical microscopy, endocrinology, toxicology, or other subspecialty specified by regulation adopted by the department.

(D) For purposes of immunohematology, means ABO/Rh Type and Group, antibody detection for transfusion, antibody detection nontransfusion, antibody identification, compatibility, or other subspecialty specified by regulation adopted by the department.

(E) For pathology, means tissue pathology, oral pathology, diagnostic cytology, or other subspecialty specified by regulation adopted by the department.

(F) For purposes of genetics, means molecular biology related to the diagnosis of human genetic abnormalities, cytogenetics, biochemical genetics, laboratory genetics, or other subspecialty specified by regulation adopted by the department.

(G) For purposes of reproductive biology, means andrology and embryology, including diagnostic testing for management of primary and secondary infertility, fertility assessment, and fertility preservation, as well as the evaluation and assessment of gametes and embryos and their associated fluids and tissues, or other subspecialty specified by regulation adopted by the department. Reproductive biology does not include the qualitative assessment of sperm in preparation for intrauterine insemination.

(b) This chapter does not restrict, limit, or prevent a person licensed to provide health care services under the laws of this state, including, but not limited to, licensed physicians and surgeons, licensed pharmacists, and registered nurses, from practicing the profession or occupation for which the person is licensed.

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

SEC. 5. Section 1207 of the Business and Professions Code is amended to read:

1207. (a) As used in this chapter, "clinical chemist," "clinical microbiologist," "clinical toxicologist," "clinical genetic molecular

biologist," "clinical cytogeneticist," "clinical laboratory geneticist," "clinical reproductive biologist," or "oral and maxillofacial pathologist" means a person licensed by the department under Section 1264 to engage in, or supervise others engaged in, clinical laboratory practice limited to the person's area of specialization or to direct a clinical laboratory, or portion thereof, limited to their area of specialization. A licensed person who is qualified under CLIA may perform clinical laboratory tests or examinations classified as of high complexity under CLIA, and the duties and responsibilities of a laboratory director, technical consultant, clinical consultant, technical supervisor, and general supervisor, as specified under CLIA, limited to their area of specialty or subspecialty as described in subdivision (b), and shall only direct a clinical laboratory providing service within those specialties or subspecialties. A person licensed as a "clinical chemist," "clinical microbiologist," "clinical toxicologist," "clinical genetic molecular biologist," "clinical cytogeneticist," "clinical laboratory geneticist," "clinical reproductive biologist," or "oral and maxillofacial pathologist" may perform any clinical laboratory test or examination classified as waived or of moderate complexity under CLIA.

(b) The specialty or subspecialty for each of the limited license categories identified in subdivision (a), and the clinical laboratories that may be directed by persons licensed in each of those categories, are the following:

(1) For a person licensed under this chapter as a clinical chemist, the specialty of chemistry and the subspecialties of routine chemistry, endocrinology, clinical microscopy, toxicology, or other specialty or subspecialty specified by regulation adopted by the department.

(2) For a person licensed under this chapter as a clinical microbiologist, the specialty of microbiology and the subspecialties of bacteriology, mycobacteriology, mycology, parasitology, virology, molecular biology, and serology for diagnosis of infectious diseases, or other specialty or subspecialty specified by regulation adopted by the department.

(3) For a person licensed under this chapter as a clinical toxicologist, the subspecialty of toxicology within the specialty of chemistry or other specialty or subspecialty specified by regulation adopted by the department.

(4) For a person licensed under this chapter as a clinical genetic molecular biologist, the subspecialty of molecular biology related to diagnosis of human genetic abnormalities within the specialty of genetics or other specialty or subspecialty specified by regulation adopted by the department.

(5) For a person licensed under this chapter as a clinical cytogeneticist, the subspecialty of cytogenetics within the specialty of genetics or other specialty or subspecialty specified by regulation adopted by the department.

(6) For a person licensed under this chapter as a clinical laboratory geneticist, the subspecialties of molecular biology related to diagnosis of human genetic abnormalities, cytogenetics, biochemical genetics, or laboratory genetics within the specialty of genetics, or other specialty or subspecialty specified by regulation adopted by the department.

(7) For a person licensed under this chapter as a clinical reproductive biologist, the specialty of reproductive biology and the subspecialties of

andrology and embryology related to diagnostic testing for management of primary and secondary infertility, fertility assessment, and fertility preservation, as well as the evaluation and assessment of gametes, embryos, and their associated fluids and tissues, or other specialty or subspecialty specified by regulation adopted by the department.

(8) For a person licensed under this chapter as an oral and maxillofacial pathologist, the subspecialty of oral pathology within the specialty of pathology or other specialty or subspecialty specified by regulation adopted by the department.

SEC. 6. Section 1210 of the Business and Professions Code is amended to read:

1210. (a) As used in this chapter, "clinical chemist scientist," "clinical microbiologist scientist," "clinical toxicologist scientist," "clinical immunohematologist scientist," "clinical genetic molecular biologist scientist," "clinical cytogeneticist scientist," "clinical laboratory geneticist scientist," "clinical reproductive biologist scientist," and "clinical histocompatibility scientist" means a person, other than a person licensed to direct a clinical laboratory, or licensed as a clinical laboratory scientist or trainee, who is licensed under Sections 1261, 1261.5, and 1262 to engage in clinical laboratory practice. The licensed person who is qualified under CLIA may perform clinical laboratory tests classified as of high complexity under CLIA and the duties and responsibilities of a technical consultant, clinical consultant, technical supervisor, and general supervisor limited to the specialty or subspecialty as identified in subdivision (b) for which the person is licensed by the department. A person licensed as a "clinical chemist scientist," "clinical microbiologist scientist," "clinical toxicologist scientist," "clinical immunohematologist scientist," "clinical genetic molecular biologist scientist," "clinical cytogeneticist scientist," "clinical laboratory geneticist scientist," "clinical reproductive biologist scientist," or a "clinical histocompatibility scientist" may perform any clinical laboratory test or examination classified as waived or of moderate complexity under CLIA.

(b) The specialties and subspecialties included in each of the license categories identified in subdivision (a), are the following:

(1) For a person licensed under this chapter as a clinical chemist scientist, the specialty of chemistry and the subspecialties of routine chemistry, endocrinology, clinical microscopy, toxicology, or other specialty or subspecialty specified by regulation adopted by the department.

(2) For a person licensed under this chapter as a clinical microbiologist scientist, the specialty of microbiology and the subspecialties of bacteriology, mycobacteriology, mycology, parasitology, virology, or molecular biology and serology for diagnosis of infectious diseases, or other specialty or subspecialty specified by regulation adopted by the department.

(3) For a person licensed under this chapter as a clinical toxicologist scientist, the subspecialty of toxicology within the specialty of chemistry or other specialty or subspecialty specified by regulation adopted by the department.

(4) For a person licensed under this chapter as a clinical genetic molecular biologist scientist, the subspecialty of molecular biology related to the diagnosis of human genetic abnormalities within the specialty of genetics, or other specialty or subspecialty specified by regulation adopted by the department.

(5) For a person licensed under this chapter as a clinical cytogeneticist scientist, the subspecialty of cytogenetics within the specialty of genetics or other specialty or subspecialty specified by regulation adopted by the department.

(6) For a person licensed under this chapter as a clinical laboratory geneticist scientist, the subspecialties of molecular biology related to diagnosis of human genetic abnormalities, cytogenetics, biochemical genetics, or laboratory genetics within the specialty of genetics or other specialty or subspecialty specified by regulation adopted by the department.

(7) For a person licensed under this chapter as a clinical reproductive biologist scientist, the specialty of reproductive biology and the subspecialties of andrology and embryology related to diagnostic testing for management of primary and secondary infertility, fertility assessment, and fertility preservation, as well as the evaluation and assessment of gametes, embryos, and their associated fluids and tissues, or other specialty or subspecialty specified by regulation adopted by the department.

(8) For a person licensed under this chapter as a clinical immunohematologist scientist, the specialty of immunohematology or other specialty or subspecialty specified by regulation adopted by the department.

(9) For a person licensed under this chapter as a clinical histocompatibility scientist, the specialty of histocompatibility or other specialty or subspecialty specified by regulation adopted by the department.

(c) Clinical chemist scientists, clinical microbiologist scientists, clinical toxicologist scientists, clinical immunohematologist scientists, clinical genetic molecular biologist scientists, clinical cytogeneticist scientists, clinical laboratory geneticist scientists, clinical reproductive biologist scientists, and clinical histocompatibility scientists shall engage in clinical laboratory practice authorized by their licensure only under the overall operation and administration of a laboratory director.

SEC. 6.5. Section 1210 of the Business and Professions Code is amended to read:

1210. (a) As used in this chapter, “clinical chemist scientist,” “clinical microbiologist scientist,” “clinical toxicologist scientist,” “clinical immunohematologist scientist,” “clinical genetic molecular biologist scientist,” “clinical cytogeneticist scientist,” “clinical laboratory geneticist scientist,” “clinical reproductive biologist scientist,” and “clinical histocompatibility scientist” means a person, other than a person licensed to direct a clinical laboratory, or licensed as a clinical laboratory scientist or trainee, who is licensed under Sections 1261, 1261.5, and 1262 to engage in clinical laboratory practice. The licensed person who is qualified under CLIA may perform clinical laboratory tests classified as of high complexity under CLIA and the duties and responsibilities of a technical consultant,

clinical consultant, technical supervisor, and general supervisor limited to the specialty or subspecialty as identified in subdivision (b) for which the person is licensed by the department. A person licensed as a "clinical chemist scientist," "clinical microbiologist scientist," "clinical toxicologist scientist," "clinical immunohematologist scientist," "clinical genetic molecular biologist scientist," "clinical cytogeneticist scientist," "clinical laboratory geneticist scientist," "clinical reproductive biologist scientist," or a "clinical histocompatibility scientist" may perform any clinical laboratory test or examination classified as waived or of moderate complexity under CLIA.

(b) The specialties and subspecialties included in each of the license categories identified in subdivision (a), are the following:

(1) For a person licensed under this chapter as a clinical chemist scientist, the specialty of chemistry and the subspecialties of routine chemistry, endocrinology, clinical microscopy, toxicology, or other specialty or subspecialty specified by regulation adopted by the department.

(2) For a person licensed under this chapter as a clinical microbiologist scientist, the specialty of microbiology and the subspecialties of bacteriology, mycobacteriology, mycology, parasitology, virology, or molecular biology and serology for diagnosis of infectious diseases, or other specialty or subspecialty specified by regulation adopted by the department.

(3) For a person licensed under this chapter as a clinical toxicologist scientist, the subspecialty of toxicology within the specialty of chemistry or other specialty or subspecialty specified by regulation adopted by the department.

(4) For a person licensed under this chapter as a clinical genetic molecular biologist scientist, the subspecialty of molecular biology related to the diagnosis of human genetic abnormalities within the specialty of genetics, or other specialty or subspecialty specified by regulation adopted by the department.

(5) For a person licensed under this chapter as a clinical cytogeneticist scientist, the subspecialty of cytogenetics within the specialty of genetics or other specialty or subspecialty specified by regulation adopted by the department.

(6) For a person licensed under this chapter as a clinical laboratory geneticist scientist, the subspecialties of molecular biology related to diagnosis of human genetic abnormalities, cytogenetics, biochemical genetics, or laboratory genetics within the specialty of genetics or other specialty or subspecialty specified by regulation adopted by the department.

(7) For a person licensed under this chapter as a clinical reproductive biologist scientist, the specialty of reproductive biology and the subspecialties of andrology and embryology related to diagnostic testing for management of primary and secondary infertility, fertility assessment, and fertility preservation, as well as the evaluation and assessment of gametes, embryos, and their associated fluids and tissues, or other specialty or subspecialty specified by regulation adopted by the department.

(8) For a person licensed under this chapter as a clinical immunohematologist scientist, the specialty of immunohematology or other specialty or subspecialty specified by regulation adopted by the department.

(9) For a person licensed under this chapter as a clinical histocompatibility scientist, the specialty of histocompatibility or other specialty or subspecialty specified by regulation adopted by the department.

(c) Clinical chemist scientists, clinical microbiologist scientists, clinical toxicologist scientists, clinical immunohematologist scientists, clinical genetic molecular biologist scientists, clinical cytogeneticist scientists, clinical laboratory geneticist scientists, clinical reproductive biologist scientists, and clinical histocompatibility scientists shall engage in clinical laboratory practice authorized by their licensure only under the overall operation and administration of a laboratory director.

(d) A person licensed under this chapter as a clinical genetic molecular biologist scientist may use molecular biology techniques to perform a clinical laboratory test or examination for the detection of any disease affecting humans.

SEC. 7. Section 1261 of the Business and Professions Code is amended to read:

1261. (a) (1) The department shall issue a clinical laboratory scientist's or a limited clinical laboratory scientist's license to each person who is a lawful holder of a baccalaureate or an equivalent or higher degree, who has applied for the license on forms provided by the department and has met the requirements of this chapter and any reasonable qualifications established by regulations of the department. However, an exception to the degree requirement may be made by the department for the clinical laboratory scientist's license only if the applicant for the license has completed a minimum of two years of experience as a licensed trainee or the equivalent thereof, as determined by the department, doing clinical laboratory work embracing the various fields of clinical laboratory activity in a clinical laboratory approved by the department. In addition, the applicant applying under this section must have 90 semester hours or equivalent quarter hours of university or college work or the equivalent thereof, as may be determined by the department, which shall have included at least 23 semester hours or equivalent quarter hours of science courses as specified by regulations of the department. Additional college or university work that includes courses in the fundamental sciences may be substituted for one of the two years of experience in the ratio of 30 semester hours or equivalent quarter hours for each year of experience. This exception shall not apply to the limited clinical laboratory scientist's license. The department shall hold examinations to aid it in judging the qualifications of applicants. Licenses may be issued in any or all of the sciences applied in a clinical laboratory as determined by regulation established by the department. The department shall establish by regulation the college courses or majors to be included in the college or university training and the amount and kind of training or experience required. Examinations, training, or experience requirements for limited licenses shall cover only the science concerned. The department may identify

by regulation the appropriate sciences and shall establish the minimum requirements for training and experience and required courses or major for each.

(2) Prior to the adoption of implementing regulations and notwithstanding subdivision (c) of Section 1261.5, the department shall issue a clinical reproductive biologist scientist license to every applicant for licensure who has applied for the license on forms provided by the department, who holds a baccalaureate or an equivalent or higher degree in a chemical, physical, or biological science or clinical laboratory science, who is certified as an andrology laboratory scientist, an embryology laboratory scientist, or a technical supervisor of andrology or embryology by a certifying board in the specialty of reproductive biology, clinical andrology, or clinical embryology approved by the department, and who meets the qualifications of training, education, and experience specified in Section 1261.5.

(3) Prior to the adoption of implementing regulations and notwithstanding subdivision (c) of Section 1261.5, the department shall issue a clinical laboratory geneticist scientist license to every applicant for licensure who has applied for the license on forms provided by the department, who holds a baccalaureate or an equivalent or higher degree in a chemical, physical, or biological science, clinical laboratory science, or a field related to genetics, who is certified in biochemical genetics or laboratory genetics and genomics by a certifying board in the specialty of genetics approved by the department, and who meets the qualifications of training, education, and experience specified in Section 1261.5.

(4) Experience as a clinical laboratory technician in any branch of the Armed Forces of the United States may be considered equivalent to the experience as a trainee, if the experience is approved by the department. Each year of training and experience as a clinical laboratory technician in the armed forces shall be equivalent to 15 semester hours, which shall be credited to the minimum number of hours required to qualify for licensure as a trainee. The semester hours acquired in this manner shall not consist of the science courses required by the department under this section. The maximum number of hours granted shall not exceed 60 semester hours or its equivalent.

(b) (1) Notwithstanding subdivision (a), the department shall establish an "MLT-to-CLS" pathway program by January 1, 2022, that would authorize a licensed MLT to apply their work experience and training from a department-approved MLT training program towards the completion of a CLS training program. The work experience and training may only be eligible for the pathway program upon approval by the department.

(2) For purposes of this subdivision:

(A) "CLS" means a clinical laboratory scientist.

(B) "MLT" means a medical laboratory technician.

SEC. 8. Section 1261.5 of the Business and Professions Code is amended to read:

1261.5. (a) The department may issue limited clinical laboratory scientist's licenses in chemistry, microbiology, toxicology,

histocompatibility, immunohematology, genetic molecular biology, cytogenetics, laboratory genetics, reproductive biology, or other areas of laboratory specialty or subspecialty when determined to be necessary by the department in order for licensure categories to keep abreast of changes in laboratory or scientific technology. Whenever the department determines that a new limited clinical laboratory scientist license category is necessary, it shall adopt regulations identifying the category and the areas of specialization included within the category.

(b) To qualify for admission to the examination for a special clinical laboratory scientist's license, an applicant shall have both the following:

(1) Graduated from a college or university maintaining standards equivalent, as determined by the department, to those institutions accredited by the Western Association of Schools and Colleges or an essentially equivalent accrediting agency with a baccalaureate or higher degree with a major appropriate to the field for which a license is being sought.

(2) One year of full-time postgraduate training or experience in the various areas of analysis in the field for which a license is being sought in a laboratory that has a license issued under this chapter or which the department determines is equivalent thereto.

(c) Whenever a limited clinical laboratory scientist's license is established for a specific area of specialization, the department may issue the license without examination to applicants who had met standards of education and training, defined by regulations, and to applicants certified by a board approved for that certification by the department, prior to the date of the adoption of implementing regulations.

(d) The department shall adopt regulations to implement this section.

SEC. 9. Section 1264 of the Business and Professions Code is amended to read:

1264. (a) (1) The department shall issue a clinical chemist, clinical microbiologist, clinical toxicologist, clinical genetic molecular biologist, clinical laboratory geneticist, clinical reproductive biologist, or clinical cytogeneticist license to each person who has applied for the license on forms provided by the department, who is a lawful holder of a master of science or doctoral degree in the specialty for which the applicant is seeking a license, and who has met the additional reasonable qualifications of training, education, and experience as the department may establish by regulations.

(2) The department shall issue a clinical reproductive biologist license to an applicant for licensure who has applied for the license on forms provided by the department, who holds a master of science degree in a chemical, physical, or biological science or clinical laboratory science, who was board certified as a Reproductive Biology Laboratory Director, Andrology Laboratory Director, Embryology Laboratory Director, or High-Complexity Clinical Laboratory Director by the American Board of Bioanalysis before July 1, 2020, who has passed an oral and written examination conducted by the department or a committee designated by the department to conduct the examination, and who meets any additional and

reasonable qualifications of training, education, and experience as the department may establish by regulations.

(3) Prior to the adoption of implementing regulations and notwithstanding subdivision (c), the department shall issue a clinical reproductive biologist license to an applicant for licensure who meets each of the following:

(A) Has applied for the license on forms provided by the department.

(B) Holds a master of science in a chemical, physical, or biological science or clinical laboratory science, and was board certified as a Reproductive Biology Laboratory Director, Andrology Laboratory Director, Embryology Laboratory Director, or High-Complexity Clinical Laboratory Director by the American Board of Bioanalysis before July 1, 2020, or holds a doctoral degree in a chemical, physical, or biological science or clinical laboratory science and is board certified as a Reproductive Biology Laboratory Director, Embryology Laboratory Director, or High-Complexity Clinical Laboratory Director by the American Board of Bioanalysis or other certifying board in clinical reproductive biology, clinical andrology, or clinical embryology approved by the department.

(C) Has passed an oral and written examination conducted by the department or a committee designated by the department to conduct the examination.

(D) Meets the qualifications of training, education, and experience specified in subdivision (b).

(4) Prior to the adoption of implementing regulations and notwithstanding subdivision (c), the department shall issue a clinical laboratory geneticist license to an applicant who meets each of the following:

(A) Has applied for the license on forms provided by the department.

(B) Holds a doctoral degree in a chemical, physical, or biological science, clinical laboratory science, or a field related to genetics.

(C) Is certified as a diplomate in laboratory genetics and genomics or clinical biochemical genetics by the American Board of Medical Genetics and Genomics or other certifying board in the specialty of genetics approved by the department.

(D) Has passed an oral and written examination conducted by the department or a committee designated by the department to conduct the examination.

(E) Meets the qualifications of training, education, and experience specified in subdivision (b).

(5) The department shall issue an oral and maxillofacial pathologist license to every applicant for licensure who has applied for the license on forms provided by the department, who is a registered Diplomate of the American Board of Oral and Maxillofacial Pathology, and who meets any additional and reasonable qualifications of training, education, and experience as the department may establish by regulation.

(b) The graduate education shall have included 30 semester hours of coursework in the applicant's specialty. Applicants possessing only a master of science degree shall have the equivalent of one year of full-time, directed study or training in procedures and principles involved in the development,

modification, or evaluation of laboratory methods, including training in complex methods applicable to diagnostic laboratory work. Each applicant shall have had one year of training in their specialty in a clinical laboratory acceptable to the department and three years of experience in their specialty in a clinical laboratory, two years of which must have been at a supervisory level. The education shall have been obtained in one or more established and reputable institutions maintaining standards equivalent, as determined by the department, to those institutions accredited by an agency acceptable to the department. The department shall determine by oral and written examination conducted by the department, or a committee designated by the department, that the applicant is properly qualified. Examinations, training, or experience requirements for specialty licenses shall cover only the specialty concerned.

(c) The department may issue licenses without examination to applicants who have passed examinations of other states or national accrediting boards whose requirements are equal to or greater than those required by this chapter and regulations established by the department. The evaluation of other state requirements or requirements of national accrediting boards shall be carried out by the department with the assistance of representatives from the licensed groups. This section does not apply to persons who have passed an examination by another state or national accrediting board before the establishment of requirements that are equal to or exceed those of this chapter or regulations of the department.

(d) The department may issue licenses without examination to applicants who had met standards of education and training, defined by regulations, before the date of the adoption of implementing regulations.

(e) The department shall adopt regulations to conform to this section.

SEC. 10. Section 1300 of the Business and Professions Code is amended to read:

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

(a) The application fee for a histocompatibility laboratory director's, clinical laboratory bioanalyst's, clinical chemist's, clinical microbiologist's, clinical laboratory toxicologist's, clinical genetic molecular biologist's, clinical cytogeneticist's, clinical laboratory geneticist's, or clinical reproductive biologist's license, or license for another specialty or subspecialty specified by regulation adopted by the department, is sixty-three dollars ($63).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(t) On or before July 1, 2013, the department shall report to the Legislature during the annual legislative budget hearing process the extent

to which the state oversight program meets or exceeds federal oversight standards and the extent to which the federal Department of Health and Human Services is accepting exemption applications and the potential cost to the state for an exemption.

SEC. 11. (a) Section 4.5 of this bill incorporates amendments to Section 1206 of the Business and Professions Code proposed by both this bill and Assembly Bill 1328. That section shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2023, (2) each bill amends Section 1206 of the Business and Professions Code, and (3) this bill is enacted after Assembly Bill 1328, in which case Section 4 of this bill shall not become operative.

(b) Section 6.5 of this bill incorporates amendments to Section 1210 of the Business and Professions Code proposed by this bill and Assembly Bill 2107. That section shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2023, (2) each bill amends Section 1210 of the Business and Professions Code, and (3) this bill is enacted after Assembly Bill 2107, in which case Section 1210 of the Business and Professions Code, as amended by Assembly Bill 2107, shall remain operative only until the operative date of this bill, at which time Section 6.5 of this bill shall become operative, and Section 6 of this bill shall not become operative.

SEC. 12. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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