SB-1500 Public health: federal regulation. (2021-2022)

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Senate Bill No. 1500

CHAPTER 955

An act to amend Sections 1602.5, 1609, 1635.1, and 111656.1 of the Health and Safety Code, relating to public health.

[Approved by Governor September 30, 2022. Filed with Secretary of State September 30, 2022.]

LEGISLATIVE COUNSEL'S DIGEST

SB 1500, Committee on Health. Public health: federal regulation.

The Sherman Food, Drug, and Cosmetic Law regulates the packaging, labeling, and advertising of drugs and devices, and is administered by the State Department of Public Health. The law prohibits the sale, delivery, or giving away of any new drug or new device unless either the department has approved a new drug or device application for that new drug or new device and that approval has not been withdrawn, terminated, or suspended under specified provisions of the federal Food, Drug, and Cosmetic Act, or it is a new device for which a premarket approval application has been approved, and that approval has not been withdrawn, terminated, or suspended under the federal act. Existing law exempts a drug or device intended solely for investigational use of a drug or device if the investigation is conducted in accordance with specified provisions of the federal act.

Existing law prohibits the production of human whole blood or human whole blood derivatives unless the person is licensed and the human whole blood or human whole blood derivative is collected, prepared, labeled, and stored, as specified. Existing law exempts the production of biologics other than human whole blood and human whole blood derivatives if the biologics are produced in a federally licensed facility.

This bill would exempt the production of human whole blood and human whole blood derivatives and other biologics at a clinical trial site, as specified, if the biologics are intended solely for investigation use and the investigation is conducted in accordance with specified provisions of the federal Food, Drug, and Cosmetic Act.

Existing law requires every tissue bank operating in California to have a current and valid tissue bank license, unless a tissue bank falls under a specified exemption.

This bill would additionally exempt the storage or preparation for patient administration of tissue performed at a clinical trial site that is intended solely for investigation use and the investigation is conducted in accordance with specified provisions of the federal Food, Drug, and Cosmetic Act.

The Sherman Food, Drug, and Cosmetic Law, until January 1, 2023, exempts a licensed home medical device retail facility business from annual inspection, if it is accredited, as specified, by an accreditation organization approved by the federal Centers for Medicare and Medicaid Services and authorizes the department to inspect only upon a complaint about the licensee. For a licensee that is not so accredited, existing law requires the department to conduct an inspection at least annually.

This bill would extend these provisions until January 1, 2028.

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: no

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 1602.5 of the Health and Safety Code is amended to read:

1602.5. (a) No person shall engage in the production of human whole blood or human whole blood derivatives unless the person is licensed under this chapter and the human whole blood or human whole blood derivative is collected, prepared, labeled, and stored in accordance with both of the following:

(1) The standards set forth in the 13th Edition of "Standards for Blood Banks and Transfusion Services," as published by the American Association of Blood Banks and in effect on November 15, 1989, or any amendments thereto or later published editions or amendments thereto. These shall be the standards for all licensed blood banks and blood transfusion services in the state.

(2) Those provisions of Title 17 of the California Code of Regulations that are continued in effect by subdivision (c) or that are adopted pursuant to subdivision (b).

(b) The department may, by the adoption of regulations, establish and require compliance with requirements in addition to, or in lieu of, those in subdivision (a) as the department deems appropriate to reflect changing technology or to improve the safety of human whole blood or human whole blood derivatives. Any standards adopted pursuant to this subdivision shall be adopted after consultation with representatives of the American Association of Blood Banks.

(c) Until the time superseded by any regulation adopted pursuant to this section, all of the provisions of Group 1 (commencing with Section 950) of Subchapter 1 of Chapter 2 of Part 1 of Title 17 of the California Code of Regulations shall remain in effect with the exception of the following:

(1) Subdivisions (i) to (k), inclusive, of Section 997.

(2) Sections 999 and 1001.

(3) Subdivisions (a) to (c), inclusive, of Section 1002.

(4) Paragraphs (2) and (3) of subdivision (e) of Section 1002.

(5) Subdivisions (f) and (g) of Section 1002.

(6) Paragraphs (2) to (6), inclusive, of subdivision (h) of Section 1002.

(7) Subdivisions (i), (k), and (l) of Section 1002.

(8) Subdivisions (a) to (c), inclusive, of Section 1004.

(9) Sections 1010, 1012, 1013, 1014, 1024, and 1024.1.

(10) Subdivisions (a), (b), and (e) of Section 1025.

(11) Paragraphs (1) to (3), inclusive, of subdivision (c) of Section 1025.

(d) (1) Any amendment to the 13th Edition of "Standards for Blood Banks and Transfusion Services," any later editions, or any amendments thereto, published by the American Association of Blood Banks shall become effective in California 90 days after the effective date of this section, or 90 days after publication by the association, unless the department sends written notice, within such a 90-day period, to all persons licensed under this chapter to engage in the production of human whole blood or human whole blood derivatives, indicating which portions shall not become effective.

(2) The department may determine that no portion of any amendments or later editions shall become effective. The department shall determine that no portion of an amendment or later edition shall become effective pursuant to this section whenever the department has not received a copy of the amendment or later edition by the date it is published by the American Association of Blood Banks.

(e) This section does not apply to a clinical trial site storing or preparing for patient administration human whole blood and human whole blood derivatives intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs or devices if the investigation is conducted in accordance with the requirements of Section 505(i) of the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 355(i)) or Section 520(g) thereof (21 U.S.C. Sec. 360j(g)) and the regulations adopted pursuant to the federal act.

SEC. 2. Section 1609 of the Health and Safety Code is amended to read:

1609. No person shall engage in the production of biologics other than human whole blood and human whole blood derivatives unless:

(a) In a laboratory licensed by the Public Health Service, United States Department of Health, Education and Welfare.

(b) In a laboratory licensed by the Animal Inspection and Quarantine Branch, Agricultural Research Service, United States Department of Agriculture.

(c) In a clinical trial site storing or preparing for patient administration biologics, other than human whole blood and human whole blood derivatives, intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs or devices if the investigation is conducted in accordance with the requirements of Section 505(i) of the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 355(i)) or Section 520(g) thereof (21 U.S.C. Sec. 360j(g)) and the regulations adopted pursuant to the federal act.

(d) Under the provisions of this chapter.

SEC. 3. Section 1635.1 of the Health and Safety Code is amended to read:

1635.1. (a) Except as provided in subdivision (b), every tissue bank operating in California on or after July 1, 1992, shall have a current and valid tissue bank license issued or renewed by the department pursuant to Section 1639.2 or 1639.3.

(b) This chapter does not apply to any of the following:

(1) The collection, processing, storage, or distribution of human whole blood or its derivatives by blood banks licensed pursuant to Chapter 4 (commencing with Section 1600) or any person exempt from licensure under that chapter.

(2) The collection, processing, storage, or distribution of tissue for autopsy, biopsy, training, education, or for other medical or scientific research or investigation, when transplantation of the tissue is not intended or reasonably foreseeable.

(3) The collection of tissue by an individual physician and surgeon from their patient or the implantation of tissue by an individual physician and surgeon into their patient. This exemption shall not be interpreted to apply to any processing or storage of the tissue, except for the processing and storage of semen by an individual physician and surgeon when the semen was collected by that physician and surgeon from a semen donor or obtained by that physician and surgeon from a tissue bank licensed under this chapter.

(4) The collection, processing, storage, or distribution of fetal tissue or tissue derived from a human embryo or fetus.

(5) The collection, processing, storage, or distribution by an organ procurement organization (OPO), as defined in Section 486.302 of Title 42 of the Code of Federal Regulations, if the OPO, at the time of collection, processing, storage, and distribution of the tissue, has been designated by the Secretary of Health and Human Services as an OPO and meets the requirements of Sections 486.304 and 486.306 of Title 42 of the Code of Federal Regulations, as applicable.

(6) The storage of prepackaged, freeze-dried bone by a general acute care hospital.

(7) The storage of freeze-dried bone and dermis by any licensed dentist practicing in a lawful practice setting, if the freeze-dried bone and dermis have been obtained from a licensed tissue bank, are stored in strict accordance with a kit's package insert and any other manufacturer instructions and guidelines, and are used for the express purpose of implantation into a patient.

(8) The storage of a human cell, tissue, or cellular- or tissue-based product (HCT/P), as defined by the federal Food and Drug Administration (FDA), that is either a medical device approved pursuant to Section 510 or 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 360 et seq.) or that is a biologic product approved under Section 351 of the federal Public Health Service Act (42 U.S.C. Sec. 262) by a licensed physician or podiatrist acting within the scope and authority of their license and practicing in a lawful practice setting. The medical device or biologic product must have been obtained from a California-licensed tissue bank, been stored in strict accordance with the device's or product's package insert and any other manufacturer instructions, and used solely for the express purpose of direct implantation into or application on the practitioner's own patient. In order to be eligible for the exemption in this paragraph, the entity or organization where the physician or podiatrist who is eligible for the exemption is practicing shall notify the department, in writing, that the practitioner is licensed and meets the requirements of this paragraph. The notification shall include all of the following:

(A) A list of all practitioners to whom the notice applies.

(B) Acknowledgment that each listed practitioner uses the medical device or biologic product in the scope and authority of their license and practice for the purposes of direct patient care as described in this paragraph.

(C) A statement that each listed practitioner agrees to strictly abide by the directions for storage in the device's or product's package insert and any other manufacturer instructions and guidelines.

(D) Acknowledgment by each practitioner that the medical device or biologic product shall not be resold or distributed.

(9) The collection, processing, storage, or distribution of any organ, as defined in paragraph (2) of subdivision (c) of Section 1635, within a single general acute care hospital, as defined in subdivision (a) of Section 1250, operating a Medicare-approved transplant program.

(10) The storage of allograft tissue by a person if all of the following apply:

(A) The person, as defined in Section 1635, is a hospital, or an outpatient setting regulated by the Medical Board of California pursuant to Chapter 1.3 (commencing with Section 1248), including an ambulatory surgical center.

(B) The person maintains a log that includes the date on which the allograft tissue was received, the expiration date of the allograft tissue, the date on which each allograft tissue is used for clinical purposes, and the disposition of any allograft tissue samples that remain unused at the time the allograft tissue expires.

(C) The allograft tissue meets all of the following:

(i) The allograft tissue was obtained from a tissue bank licensed by the state.

(ii) Each allograft tissue is individually boxed and labeled with a unique identification number and expiration date so that opening the shipping container will not disturb or otherwise alter any of the allograft tissue that is not being utilized.

(iii) The allograft tissue is intended for the express purpose of implantation into or application on a patient.

(iv) The allograft tissue is not intended for further distribution.

(v) The allograft tissue is registered with the FDA and designated to be maintained at ambient room temperature requiring no refrigeration.

(11) The storage or preparation for patient administration of tissue performed at a clinical trial site that is intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs or devices if the investigation is conducted in accordance with the requirements of Section 505(i) of the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 355(i)) or Section 520(g) thereof (21 U.S.C. Sec. 360j(g)) and the regulations adopted pursuant to the federal act.

SEC. 4. Section 111656.1 of the Health and Safety Code, as amended by Section 1 of Chapter 213 of the Statutes of 2017, is amended to read:

111656.1. (a) (1) After January 1, 2002, prior to issuing a license required by Section 111656, the department shall inspect each place of business to determine ownership, adequacy of facilities, and personnel qualifications. Nothing in this section shall prohibit the department from inspecting any medical device retail facility prior to January 1, 2002.

(2) (A) After the initial inspection pursuant to paragraph (1), the department shall inspect a licensee that is accredited by an accreditation organization approved by the federal Centers for Medicare and Medicaid Services, or its successor entity, only upon a complaint made to the department regarding the licensee.

(B) A licensee shall only be deemed to be accredited and subject to inspection pursuant to subparagraph (A) if all of the following conditions exist:

(i) The licensee is accredited by the accrediting organization at least every three years.

(ii) The licensee is subject to unannounced onsite midcycle surveys by the accrediting organization to validate ongoing compliance.

(iii) Within 30 days following an inspection by the accrediting organization, the accrediting organization notifies the department regarding the status of the licensee's accreditation.

(iv) If the licensee is less than fully accredited, the accrediting organization notifies the department of the reasons for the lack of full accreditation and any corrective action plan recommended to the licensee.

(C) The department shall inspect a licensee that ceased to be accredited in compliance with subparagraph (B) pursuant to paragraph (3).

(3) The department shall inspect a licensee that is not accredited by an accreditation organization approved by the federal Centers for Medicare and Medicaid Services, or its successor entity, at least annually.

(b) The annual license fee for a home medical device retail facility shall be eight hundred fifty dollars ($850) until adjusted pursuant to subdivision (c).

(c) The annual license fee required by Sections 111656 and 111630 shall be adjusted annually, commencing July 1, 2003, by the department so that license fee revenues cover the estimated licensing program costs. Adjusted fee amounts shall take into account the resources required for inspections and other activities to support licensing during the previous year and shall take into account projected workload and changes in department overhead costs during the upcoming year.

(d) Commencing July 1, 2003, the department shall by July 30 of each year, publish the amount of fees to be charged as adjusted pursuant to this section. This adjustment of fees shall not be subject to the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

(e) Commencing January 1, 2003, the department shall, on or before January 10 of each year, provide the Legislature with a report recommending fee rates. The report shall describe the estimated licensing program costs for the next fiscal year to carry out the licensing, regulating, inspecting, and other duties and responsibilities of the department in carrying out the provisions of this article. The department shall describe the projected license fee amount so that license fee revenues cover the estimated licensing program costs. Projected fee amounts shall take into account the resources required for inspections and other activities to support licensing during the previous year and shall take into account projected workload and changes in department overhead costs during the upcoming year.

(f) The Drug and Device Safety Fund is hereby created as a special fund in the State Treasury. All moneys collected by the department under this section and Sections 111656.7, 111656.8, 111656.12, and 111630, and fines and penalties collected by the department in the enforcement of this article, shall be deposited in the fund for use by the department upon appropriation by the Legislature for the purposes of providing funds necessary to carry out and implement the provisions of this article relating to drugs and devices.

(g) This section shall remain in effect only until January 1, 2028, and as of that date is repealed.

SEC. 5. Section 111656.1 of the Health and Safety Code, as added by Section 2 of Chapter 213 of the Statutes of 2017, is amended to read:

111656.1. (a) Prior to issuing a license required by Section 111656, the department shall inspect each place of business to determine ownership, adequacy of facilities, and personnel qualifications. The department shall inspect each licensee at least annually thereafter.

(b) The annual license fee for a home medical device retail facility shall be eight hundred fifty dollars ($850) until adjusted pursuant to subdivision (c).

(c) The annual license fee required by Sections 111656 and 111630 shall be adjusted annually, commencing July 1, 2003, by the department so that license fee revenues cover the estimated licensing program costs. Adjusted fee amounts shall take into account the resources required for inspections and other activities to support licensing during the previous year and shall take into account projected workload and changes in department overhead costs during the upcoming year.

(d) The department shall by July 30 of each year publish the amount of fees to be charged as adjusted pursuant to this section. This adjustment of fees shall not be subject to the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

(e) The department shall, on or before January 10 of each year, provide the Legislature with a report recommending fee rates. The report shall describe the estimated licensing program costs for the next fiscal year to carry out the licensing, regulating, inspecting, and other duties and responsibilities of the department in carrying out the provisions of this article. The department shall describe the projected license fee amount so that license fee revenues cover the estimated licensing program costs. Projected fee amounts shall take into account the resources required for inspections and other activities to support licensing during the previous year and shall take into account projected workload and changes in department overhead costs during the upcoming year.

(f) The Drug and Device Safety Fund is hereby created as a special fund in the State Treasury. All moneys collected by the department under this section and Sections 111656.7, 111656.8, 111656.12, and 111630, and fines and penalties collected by the department in the enforcement of this article, shall be deposited in the fund for use by the department upon appropriation by the

Legislature for the purposes of providing funds necessary to carry out and implement the provisions of this article relating to drugs and devices.

(g) This section shall become operative on January 1, 2028.