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HEALTH AND SAFETY CODE - HSC

DIVISION 2. LICENSING PROVISIONS [1200 - 1796.70] (*Division 2 enacted by Stats. 1939, Ch. 60.*)

CHAPTER 4.1. Tissue Banks [1635 - 1643.2] (*Chapter 4.1 added by Stats. 1991, Ch. 801, Sec. 2.*)

ARTICLE 2. Regulation of Tissue Banks [1639 - 1641.1] (*Article 2 added by Stats. 1991, Ch. 801, Sec. 2.*)

1639. (a) The department may adopt rules and regulations governing the administration and enforcement of this chapter.

(b) Regulations adopted by the department may include minimum standards for the following:

- (1) Safe preservation, transportation, storage, and handling of tissue acquired or used for transplantation.
- (2) Testing of donors to determine compatibility when appropriate.
- (3) Testing or assessment of donors to prevent the spread of disease through transplantation.
- (4) Equipment.
- (5) Methods.
- (6) Personnel qualifications.
- (7) Any other area concerning the operation or maintenance of a tissue bank, not inconsistent with this chapter, as may be necessary to carry out this chapter.

(c) The department shall report to the Legislature by January 1, 2004, on the status of the regulations developed pursuant to this section.

(*Amended by Stats. 2003, Ch. 464, Sec. 1. Effective January 1, 2004.*)

1639.01. (a) Notwithstanding Section 1639, the state department shall adopt, on or before July 1, 2004, rules and regulations governing licensed tissue banks engaged in the collection of human musculoskeletal tissue, skin, and veins for transplantation in humans. The regulations shall be substantially based upon the criteria used by tissue bank trade associations in their respective accreditation processes including, but not limited to, those of the Eye Bank Association of America and the American Association of Tissue Banks, and the scientific and technical data submitted by individual tissue banks.

(b) Regulations adopted by the state department, pursuant to subdivision (a), shall include minimum standards for all of the following:

- (1) Safe preservation, transportation, storage, and handling of tissue acquired or used for transplantation.
- (2) Testing of donors to determine compatibility when appropriate.
- (3) Testing or assessment of donors to prevent the spread of disease through transplantation.
- (4) Equipment.
- (5) Methods.
- (6) Personnel qualifications.

(7) Any other area concerning the operation or maintenance of a tissue bank, not inconsistent with this chapter, as may be necessary to carry out this chapter.

(c) On or before July 1, 2003, the department shall report to the appropriate policy and fiscal committees of the Legislature regarding the status of the proposed regulations.

(Added by Stats. 2002, Ch. 929, Sec. 1. Effective January 1, 2003.)

1639.1. Any person desiring a license issued pursuant to Section 1639.3 shall file with the state department a verified application on forms prescribed by the state department containing all of the following:

- (a) The name of the applicant for licensure.
- (b) The street address of the tissue bank. If more than one street address is occupied by the tissue bank, all occupied street addresses shall be listed.
- (c) Whether the applicant is an individual, partnership, unincorporated association, or corporation.
- (d) Whether the applicant does business under a fictitious name, and, if so, the fictitious name and the name of the locality wherein any fictitious name permit is filed.
- (e) If the applicant is a partnership, the names of all the members of the partnership, or unincorporated association, whether general or limited.
- (f) If the applicant is a corporation, the name of the officers, directors, shareholders holding a 5 percent or more interest in the corporation, and any person, partnership, or corporation who or which has the responsibility to manage or conduct the day-to-day operation of the tissue bank.
- (g) The type of tissue collected, processed, stored, or distributed by the tissue bank.
- (h) The names, titles, and qualifications of the persons responsible for the collection, processing, storage, or distribution of tissue by the tissue bank.
- (i) Any process utilized by the tissue bank to ensure safe preservation, transportation, storage, and handling, of tissue acquired or used by the tissue bank.
- (j) Any process utilized by the tissue bank to determine if, when appropriate, donors have been tested to determine compatibility.
- (k) Any process utilized by the tissue bank to determine if donors have been tested or assessed for the transmission of disease through transplantation.

(Added by Stats. 1991, Ch. 801, Sec. 2.)

1639.2. (a) Each license issued pursuant to subdivision (a) of Section 1639.3 before July 1, 1992, shall expire July 1, 1993. Every other license issued pursuant to subdivision (a) of Section 1639.3 shall expire 12 months from the date of issuance.

(b) An application for renewal of a license issued pursuant to subdivision (a) of Section 1639.3 shall be filed with the state department not less than 30 days prior to its expiration date and shall be accompanied by the annual renewal fee required in Section 1639.5. Failure to make timely application or payment for renewal shall result by operation of law in expiration of the license on its expiration date.

(c) Upon application and payment of the required fee, a renewal license issued under subdivision (a) of Section 1639.3 shall be renewed for one- or two-year periods, at the option of the licensee, as long as the licensee has been found to be in substantial compliance with this chapter and the rules and regulations adopted under this chapter during the preceding license period.

(d) Any license issued pursuant to this chapter shall be forfeited by operation of law prior to its expiration date when one of the following occurs:

- (1) The tissue bank is sold or otherwise transferred.
- (2) The license is surrendered to the state department.

(Added by Stats. 1991, Ch. 801, Sec. 2.)

1639.3. (a) Upon the filing of the verified application for licensure required by Section 1639.1, payment of the application fee in the amount required in Section 1639.5, and full compliance with this chapter and the rules and regulations adopted by the state department, the state department shall issue a license to operate a tissue bank to the applicant.

(b) If the state department finds that the applicant is not in compliance with this chapter or the rules or regulations adopted under this chapter, or if it finds that the applicant has acted in a manner which would justify the revocation or suspension of a tissue bank license as described in Section 1643, the license shall be denied.

(c) The state department may, prior to a determination under subdivision (a) that the applicant is in full compliance, but after the filing of a complete and verified application and payment of the application fee, issue a provisional license to operate a tissue bank to the applicant. The provisional license shall remain in effect until a license is either granted under subdivision (a) or denied under subdivision (b).

If this period is longer than a year from the date of filing the application for licensure, the applicant shall pay an additional annual fee of nine hundred fifty dollars (\$950) in order for the provisional license to remain in effect for an additional one-year period. Failure to pay the additional annual fee shall result, by operation of law, in automatic expiration of the provisional license one year from the date of its original issuance. If the provisional license does so expire, the applicant may not continue to operate a tissue bank pending the department's determination of whether a license shall be granted or denied.

(Added by Stats. 1991, Ch. 801, Sec. 2.)

1639.35. Any person, when submitting an application for a license, including the renewal thereof, pursuant to this chapter, shall also submit, with the application, a copy of the applicant's standard informed consent form required pursuant to Section 7158.3.

(Added by Stats. 2003, Ch. 464, Sec. 2. Effective January 1, 2004.)

1639.4. Immediately upon the denial of any application for a license, the state department shall notify the applicant in writing. Within 20 days after the state department mails the notice, the applicant may present a written petition for a hearing to the state department. Upon receipt by the state department of the petition in proper form, the petition shall be set for hearing. The proceedings shall be conducted in accordance with Section 100171.

(Amended by Stats. 1997, Ch. 220, Sec. 20. Effective August 4, 1997.)

1639.5. (a) The application and annual renewal fee for a tissue bank license shall be nine hundred fifty dollars (\$950). Upon application for renewal of a license issued pursuant to subdivision (a) of Section 1639.3, the amount of the annual renewal fee required shall be determined by the period of time for which renewal is sought, which shall be either a one- or two-year period. The amount due shall be the amount prorated to the length of time the renewal is sought, based on the annual nine hundred fifty dollar (\$950) fee.

(b) Notwithstanding subdivision (a), no license fee shall be required for any tissue bank operated by the state or any state agency, or by a district, city, county, or city and county, or any subdivision or agency thereof, or by a "mothers' milk bank," as defined in subdivision (b) of Section 14132.34 of the Welfare and Institutions Code, that has applied for tissue bank licensure prior to January 1, 1995.

(Amended by Stats. 1994, Ch. 639, Sec. 1. Effective January 1, 1995.)

1639.55. (a) There is hereby established in the State Treasury the Tissue Bank License Fund. Notwithstanding any other provision of law, if, at the end of any fiscal year, the unencumbered balance in any account in the Tissue Bank License Fund exceeds 110 percent of the amount appropriated from the account for the following fiscal year, the state department shall reduce the application and annual renewal fees which are deposited into the account. The amount of the reduction shall be sufficient to reduce the unencumbered balance in the account at the end of the following fiscal year to less than 110 percent of the amount appropriated in that fiscal year. The adjustment of fees pursuant to this section 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.

(b) The state department shall receive and account for all money received pursuant to this chapter and shall deposit it with the Treasurer who shall keep the money in the Tissue Bank License Fund.

(c) Moneys deposited to the credit of the Tissue Bank License Fund which are appropriated in the Budget Act or any other appropriation act for support of or expenditure by the state department shall be used by the state department to administer this chapter.

(d) Upon the request of the State Director of Health Services, the Director of Finance may make a loan to the Tissue Bank License Fund from funds appropriated from the General Fund for that purpose. The amount of any such loan shall be approved by the Director of Finance and be repaid under those terms and conditions as prescribed by the Director of Finance, but shall, in any event, be repaid not later than June 30, 1995.

(Added by Stats. 1991, Ch. 801, Sec. 2.)

1639.56. The department shall submit a report to the Legislature no later than January 1, 2003, including, but not limited to, examining and evaluating all of the following:

(a) Administrative expenditures of tissue banks.

(b) Current use of informed consent by tissue banks in tissue donation and recovery, including recommendations for improving and expanding informed consent policy.

(c) Full disclosure requirements by tissue banks to the donor or the person authorized to make a donation on behalf of a decedent of all potential uses of donated and recovered tissues.

(d) A system in which individuals with medically necessary conditions for which donated tissues are part of the prescribed treatment are given priority in receiving donated tissues, and the feasibility of state subsidies to implement the system.

(e) The current process for tissue recovery and distribution, including recommendations for improvement, where necessary.

(Added by Stats. 2000, Ch. 829, Sec. 1. Effective January 1, 2001.)

1639.6. (a) In order to carry out the purpose of this chapter, any duly authorized representative of the department may do any of the following:

(1) Enter or inspect on an announced or unannounced basis any building, premise, equipment, materials, records, or information at any reasonable time to secure compliance with, or prevent a violation of, this chapter or the rules or regulations adopted by the state department.

(2) Inspect, photograph, or copy any records, reports, test results, test specimens, or other information related to the requirements of this chapter or the rules or regulations adopted by the state department.

(3) Secure any sample, photograph, or other evidence from any building or premise for the purpose of enforcing this chapter or the rules or regulations adopted by the state department.

(b) The state department may require licensed tissue banks to demonstrate satisfactory performance in a proficiency testing program approved by the state department in laboratory procedures which the tissue bank performs.

(Added by Stats. 1991, Ch. 801, Sec. 2.)

1641. Any person who violates this chapter or who willfully and repeatedly violates any rule or regulation adopted under this chapter, is guilty of a misdemeanor and upon conviction thereof shall be punished by a fine not to exceed one thousand dollars (\$1,000) or by imprisonment in a county jail for a period not to exceed 180 days, or by both fine and imprisonment.

(Added by Stats. 1991, Ch. 801, Sec. 2.)

1641.1. The state department may bring an action to enjoin the violation or threatened violation of Section 1635.1 in the superior court in and for the county in which the violation occurred or is about to occur. Any proceeding under this section shall conform to the requirements of Chapter 3 (commencing with Section 525) of Title 7 of Part 2 of the Code of Civil Procedure, except that the state department shall not be required to allege facts necessary to show or tending to show lack of adequate remedy at law or irreparable damage or loss. With respect to any action brought pursuant to this section alleging actual violation of Section 1635.1, the court shall, if it finds the allegations to be true, issue its order enjoining the continuance of the violation.

(Added by Stats. 1991, Ch. 801, Sec. 2.)