# **BILL ANALYSIS**

Senate Research Center

S.B. 1160 By: Carona Health & Human Services 3-19-97 As Filed

#### **DIGEST**

Currently, Texas law contains no provisions regarding the licensing of eye banks. Hospitals, physicians, banks, or storage facilities which perform medical transplantations may all become donees of gifts of bodies or parts, as may eye banks. However, problems have arisen regarding the quality of care and the level of medical standards within this profession. S.B. 1160 ensures that Texas eye banks maintain appropriate standards for providing quality donor eye tissue for transplant and research by establishing the licensing of eye banks; providing for inspections; using the Medical Standards of the Eye Bank Association of America or another nationally recognized accrediting association; requiring eye banks to submit annual reports; authorizing the use of temporary restraining orders and injunctions when a recipient's health is under threat; and providing civil and criminal penalties for violations.

#### **PURPOSE**

As proposed, S.B. 1160 establishes the licensing of eye banks and the use of donations of gifts of bodies or parts; and provides criminal and civil penalties.

# **RULEMAKING AUTHORITY**

Rulemaking authority is granted to the Texas Board of Health in SECTION 2 (Section 693.057, Health and Safety Code) and to the Texas Department of Health in SECTION 2 (Section 693.058, Health and Safety Code) of this bill.

## **SECTION BY SECTION ANALYSIS**

SECTION 1. Amends Section 692.005, Health and Safety Code, to provide that a bank or storage facility for human organs or tissues other than eyes or corneas is authorized to become the donee of gifts of bodies or parts, and removes a hospital or physician which uses the bodies or parts for medical or dental transplantation from the list of persons who may become donees. Makes a conforming change.

SECTION 2. Amends Chapter 693, Health and Safety Code, by adding Subchapter D, as follows:

## SUBCHAPTER D. LICENSING OF EYE BANKS

Sec. 693.051. DEFINITIONS. Defines "board," "department," "eye bank," "certified eye bank," and "certified technician."

Sec. 693.052. LICENSE REQUIRED. Prohibits a person from establishing or operating an eye bank in this state without an appropriate license issued under this subchapter. Requires each eye bank to have a separate license, and provides that a license is not transferable or assignable.

Sec. 693.053. LICENSE APPLICATION AND ISSUANCE. Requires an applicant for an eye bank license to submit an application to the Texas Department of Health (department) on a form prescribed by the department accompanied by a nonrefundable fee in an amount set by the Texas Board of Health (board). Sets forth the terms by which the department is required to issue a license, and by which a license expires and may be renewed. Provides that

information regarding the licensing status of an eye bank is an open record. Sets forth the procedure regarding the licensing of an eye bank, in the event the bank is in operation as of the effective date.

Sec. 693.054. INSPECTIONS. Authorizes the department to inspect an eye bank at reasonable times if necessary to assure compliance with this subchapter.

Sec. 693.055. FEES. Requires the board to set fees imposed by this subchapter in amounts necessary to defray the cost of administering this subchapter.

Sec. 693.056. DISPOSITION OF FEES. Sets forth the terms by which all fees collected under this subchapter are required to be deposited and appropriated.

Sec. 693.057. ADOPTION OF RULES. Requires the board to adopt rules necessary to implement this subchapter, including requirements for the issuance, renewal, denial, suspension, and revocation of a license.

Sec. 693.058. MINIMUM STANDARDS. Requires the department, by rule, to prescribe as minimum standards the medical standards of the Eye Bank Association of America or another nationally recognized accredited association, and provides an alternative in the event such standards are no longer nationally recognized. Sets forth the terms by which an applicant for an eye bank license is required to be certified and recertified. Establishes the conditions by which an eye bank is required to have at least one certified eye bank technician and a medical director on staff. Provides that an eye bank licensed by the State of Texas is expected to give priority to the needs of patients in the State of Texas. Sets forth the terms by which hospitals and other agents or agencies handling donor referrals are required to handle donor referrals involving potential eye/cornea donors.

Sec. 693.059. REPORTING REQUIREMENTS. Requires each eye bank to submit an annual report to the department. Requires the report to be submitted in the form prescribed by the department, and to contain certain information.

Sec. 693.060. DENIAL, SUSPENSION, OR REVOCATION OF LICENSE. Sets forth the conditions under which the department is authorized to deny, suspend, or revoke a license.

Sec. 693.061. INJUNCTION. Authorizes the department to petition a district court for a temporary restraining order if the department finds that the violation creates an immediate threat to the health and safety of the recipients of organic material from an eye bank. Authorizes a district court, by injunction, to prohibit a person from continuing a violation; restrain or prevent the establishment or operation of an unlicensed eye bank; and grant any other injunctive relief, provided certain conditions are met. Authorizes the attorney general to institute and conduct a suit at the request of the department. Sets forth the venue for such a suit.

Sec. 693.062. CRIMINAL PENALTY. Sets forth the terms by which a person who knowingly violates this subchapter or fails to comply with an adopted rule is liable for a civil penalty.

SECTION 3. (a) Effective date: September 1, 1997. Provides that the department is required to prescribe minimum safety standards not later than December 1, 1997.

(b) Provides that an eye bank in operation before January 1, 1998, is governed by the law as it existed immediately before September 1, 1997, and that law is continued in effect for that purpose until January 1, 1998. Requires an eye bank in operation on or after January 1, 1998, to have an eye bank license.

SECTION 4. Emergency clause.