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**RULES
OF
DEPARTMENT OF COMMUNITY HEALTH**

**CHAPTER 111-8
HEALTHCARE FACILITY REGULATION**

**111-8-28
EYE BANKS**

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111-8-28-.01 Definitions.

Unless a different meaning is required by the context, the following terms as used in these regulations shall have the meaning hereinafter respectively ascribed to them:

(a) "Eye bank" means a facility which is maintained and operated for the extraction, removal, care, storage, preservation, and/or use of human eyes or parts thereof for purposes of sight preservation or restoration, medical education, instruction pertaining to sight preservation or restoration, or research.

(b) "Person" or "persons" means any individual, firm, partnership, corporation, trustee, association, or combination thereof.

(c) "Department" means the Georgia Department of Community Health.

(d) "Medical Director" means a physician who has specialized in the field of ophthalmology, is certified by the American Board of Ophthalmology and is responsible for the medical supervision of the eye bank.

Authority: O.C.G.A. §§ 31-2-4 et seq. and 31-23-1 et seq.

111-8-28-.02 Application.

Any person or persons desiring to establish an eye bank shall apply in writing to the Department for a permit. The application shall include the following information:

(a) Name of hospital or medical school;

(b) Name and qualifications of medical director of the proposed eye bank;

(c) Name of the eye bank facility;

(d) Address of the eye bank;

(e) Brief description of equipment and facilities;

(f) Concise description of scope of service to be offered;

(g) Proof of tax-exempt and non-profit status.

Authority: O.C.G.A. §§ 31-2-4 and 31-23-1 et seq.

111-8-28-.03 Approval.

(1) Upon compliance with all of the requirements for establishing an eye bank the governing authority for establishing said eye bank shall be issued a permit by the Department.

(2) It shall be unlawful to establish and operate an eye bank without a permit.

Authority: O.C.G.A. §§ 31-2-4 et seq. and 31-23-1 et seq.

111-8-28-.04 Inspection.

Inspections of facilities, equipment and operational procedures of the eye bank shall be made by the Department. If the eye bank is found to be deficient in any point in these rules and regulations, notice of these deficiencies will be given to the eye bank. Correction of such deficiencies must be accomplished for continuation of licensure.

Authority: O.C.G.A. §§ 31-2-4 et seq. and 31-23-1 et seq.

111-8-28-.05 National Standards.

In addition to the requirements of these regulations, the eye bank shall meet the current medical standards approved by the Eye Bank Association of America.

Authority: O.C.G.A. §§ 31-2-4 and 31-23-1 et seq.

111-8-28-.06 Administration.

(1) The eye bank shall be under the control of a hospital or medical school's governing authority. This control may be shared through contractual agreement with other charitable institutions.

(2) The eye bank shall have a medical director.

(3) The eye bank may receive gifts, donations and bequests for purposes stated under the law.

(4) The eye bank shall be non-profit.

(5) The eye bank shall offer, on an as-needed basis, an appropriate course in eye extractions for embalmers.

Authority: O.C.G.A. §§ 31-2-4 et seq. and 31-23-1 et seq.

111-8-28-.07 Records.

(1) All records of the eye bank shall be confidential and shall be made available only to duly authorized persons.

(2) The following records shall be kept by each eye bank:

(a) donor record; the signed and witnessed duplicate donor card of every intended donor as well as the consent form for every eye received in the eye bank must be kept on file. The consent form shall be witnessed by two (2) persons of legal majority.

(b) history record; this shall be a record of the enucleation, identification and condition of the eye or eyes. It shall include a full medical history, the cause of death, time of death, recorded time of enucleation, and when available, gross and slit lamp examination of the enucleated eye.

(3) These records shall be retained for a minimum of six (6) years.

(4) If the eye bank ceases operation, provision must be made for the retention of records in a manner acceptable to the Department.

Authority: O.C.G.A. §§ 31-2-4 and 31-23-1 et seq.

111-8-28-.08 Consent Requirements in Coroner or Medical Examiner Cases.

(1) In any case in which a donor is having an autopsy performed, the following consent requirements shall be met prior to enucleation:

(a) A decedent who may provide a suitable eye for the transplant is under the jurisdiction of a coroner or medical examiner and an autopsy is required in accordance with O.C.G.A. § 45-16-20 et seq.; or the physician has been requested, as provided by law, to perform an autopsy on a decedent who may provide a suitable eye for the transplant:

(b) The express written consent to the removal of the eye is given by the next of kin of the decedent; and

(c) The removal of the eye will not interfere with the subsequent course of an investigation or autopsy.

(2) For corneal excision the following consent requirements shall be met:

(a) The decedent from whom the tissue is to be taken is under the jurisdiction of a coroner or medical examiner pursuant to O.C.G.A. § 45-16-25;

(b) No objection by the decedent during his lifetime or after his death, by the appropriate person listed in paragraph (d) of this subsection is known to the coroner, medical examiner, or authorized official acting for the coroner at the time the tissue is removed;

(c) The person designated by the eye bank to remove the tissue is a person authorized to do so under O.C.G.A. § 31-23-5.

(d) Objection to the removal of corneal tissue may be made known to the coroner, medical examiner, hospital, funeral director, or authorized official acting for the coroner by the decedent during his lifetime or by the following persons after the decedent's death:

1. The decedent's spouse;
2. If no spouse survives him, any of the decedent's adult children;
3. If no adult children or spouse survive him, either of the decedent's parents;
4. If no parents, adult children, or spouse survive him, any of the decedent's brothers or sisters; or
5. If none of the foregoing survive him, the decedent's next of kin.

Authority: O.C.G.A. §§ 31-2-4 et seq. and 31-23-1 et seq.

111-8-28-.09 Consent Requirements in Non-Coroner or Non-Medical Examiner Cases.

Standard hospital and/or eye bank consent requirements shall be met.

Authority: O.C.G.A. §§ 31-2-4 et seq., 31-7-1 et seq. and 31-23-1.

111-8-28-.10 Persons Authorized to Extract Eyes.

Eye banks may authorize the following persons to perform eye extractions:

- (a) Any physician;
- (b) any embalmer licensed by the state of Georgia who has

completed a course in eye extraction approved by the Department;

(c) any technician trained by and authorized by the eye bank to perform extractions.

Authority: O.C.G.A. §§ 31-2-4 et seq. and 31-23-1 et seq.

111-8-28-11 Medical and Surgical Procedures.

Procedures involved in the enucleation, transportation, and storage of eye tissue shall comply with the eye bank's policies for such procedures. These procedures shall conform to the current prevailing medical standards.

Authority: O.C.G.A. §§ 31-2-4 et seq. and 31-23-1 et seq.

111-8-28-12 Shipment.

(1) Shipping of eyes shall be the fastest and most convenient transportation methods.

(2) Eyes used for transplanting purposes shall be shipped in sturdy, insulated shipping containers that will maintain a maximum temperature of 4°C. for at least 36 hours.

(3) A shipping carton, for the transportation of eyes, shall be supplied to the participating physicians by the Eye Bank and shall contain for each donated eye:

- (a) a sterile storage chamber with cotton balls.
- (b) history record card;
- (c) printed instructions for removal of eyes.

Authority: O.C.G.A. §§ 31-2-4 et seq. and 31-23-1 et seq.

111-8-28-.13 Publicity.

All publicity, with the objective of informing and educating the general public to take an active part in the eye donor program, all fund raising activities, and the solicitation of donor eye pledges, must be done by the most dignified means. Such activities shall conform to prevailing medical ethics and at a minimum provide that:

- (a) Eye tissue shall neither be bought nor sold.
- (b) Eye tissue shall be distributed without discrimination based on race, creed, color, or national origin.
- (c) Eye tissue shall be distributed only to qualified ophthalmologists on a first come, first served basis, except in an emergency.
- (d) The wishes of the immediate family shall be respected in carrying out the donor's eye pledge.
- (e) The names of donor and recipient shall not be disclosed without written consent.
- (f) Eye pledges shall be solicited in a dignified manner.
- (g) Fund raising shall be ethically conducted.
- (h) Eye banks shall not compete with one another.

Authority: O.C.G.A. §§ 31-2-4 et seq. and 31-23-1 et seq.

111-8-28-.14 Penalty.

- (1) It shall be unlawful:

(a) for any person to sell either his eyes or any parts thereof or the eyes or any parts thereof of another person or to receive any remuneration for the giving of a human eye or any part thereof;

(b) for the person or persons operating and maintaining any eye bank to sell any donated eye or donated part thereof or knowingly to extract, remove, or take possession of any human eye or part thereof for which any person received compensation or remuneration;

(c) for any person or persons to establish or operate any eye bank without approval of the Department or otherwise not in accordance with this chapter.

(2) Any person who violates any provision of O.C.G.A. § 31-23-9 shall be guilty of a misdemeanor.

Authority: O.C.G.A. §§ 31-2-4 et seq. and 31-23-9.

111-8-28-.15 Waivers, Variances, Exemptions.

(1) The Department upon petition may grant variances or waivers of specific rules and regulations as provided for in O.C.G.A. § 31-2-7, when it has been shown that the rule or regulation is not applicable or to allow experimentation and demonstration of new and innovative approaches to delivery of services.

(2) The Department may exempt classes of facilities from regulation as provided for in O.C.G.A. § 31-2-7, when regulation would not permit the purpose intended or the class of facilities is subject to similar requirements under other rules and regulations.

Authority: O.C.G.A. §§ 31-2-4 et seq. and 31-23-1 et seq.

111-8-28-.16 Enforcement.

The administration and enforcement of these rules and regulations shall be as prescribed in O.C.G.A. § 31-2-8 and as prescribed by the Georgia Administrative Procedure Act, O.C.G.A. § 50-13-1 et seq.

Authority: O.C.G.A. §§ 31-2-4 et seq., 31-23-1 et seq. and 50-13-1 et seq.