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THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 3188 Session of 1994

INTRODUCED BY M. COHEN, BELARDI, CURRY, ROBINSON, STABACK, MIHALICH, STURLA AND MANDERINO, NOVEMBER 17, 1994

REFERRED TO COMMITTEE ON HEALTH AND WELFARE, NOVEMBER 17, 1994

AN ACT

Regulating organ procurement organizations, tissue banks and eye banks; providing for licensure procedures and for an Organ and Tissue Procurement and Transplantation Advisory Board to review the status of organ, tissue and eye procurement; and prescribing duties of the Department of Health.

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The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

CHAPTER 1

GENERAL PROVISIONS

Section 101. Short title.

This act shall be known and may be cited as the Licensure of Organ Procurement Organizations, Tissue Banks and Eye Banks Act.

Section 102. Declaration of policy.

The General Assembly finds and declares as follows:

(1) The purpose of this act is to adopt licensure

standards and to identify procedures with which organ procurement organizations, tissue banks and eye banks must comply to be licensed to operate in this Commonwealth.

(2) The intent of this act is to safeguard the public health and public interest of the citizens of this Commonwealth with respect to the procurement, processing and distribution of organs, tissues and eyes.

Section 103. Definitions.

The following words and phrases when used in this act shall have the meanings given to them in this section unless the context clearly indicates otherwise:

"Adverse reaction." The patient's unfavorable physical response to the transplanted organ or tissue with regard to the transmission of infections or other diseases identified by the Organ and Tissue Procurement and Transplantation Advisory Board.

"Advisory board." The Organ and Tissue Procurement and Transplantation Advisory Board created under section 1901.

"Agency." An organ procurement organization (OPO), tissue bank or eye bank.

"Allograft." The transplantation of tissue or organ taken from one individual of the same species as the recipient but with different hereditary factors.

"Applicant." A person who has applied to the Department of Health for a license to operate an organ procurement organization, tissue bank or eye bank.

"Autograft." The removal of tissue for transplantation from one area and transplanted in a different area of the same individual.

"Batch." The specific quantity of tissue that is intended to have uniform character and quality, within specific limits, and

is produced according to a single processing protocol during the same processing cycle.

"Brain death." The determination of death under the act of December 17, 1982 (P.L.1401, No.323), known as the Uniform Determination of Death Act.

"Cardiorespiratory (cardiac) death." The cessation of life as determined under the act of December 17, 1982 (P.L.1401, No.323), known as the Uniform Determination of Death Act.

"Certified" or "certification." The process by which agencies are licensed by the Department of Health.

"Clean, nonsterile." The use of methods and techniques that reduce gross contamination.

"Coercion." The exercise of undue influence so that free choice of donation is diminished or lost.

"Compensation." Monetary payment or other forms of retribution for a donation.

"Container (final container)." The immediate unit, bottle, vial, ampule, tube or other receptacle containing grafts as distributed.

"Coordinators." Registered nurses, physician's assistants or other appropriately trained personnel who assist in the medical management of organ donors or in the surgical procurement of organs, tissues or eyes for transplantation or research.

"Department." The Department of Health of the Commonwealth.

"Designee." One who has been assigned a duty or duties and who has the necessary training and educational qualifications to act on behalf of an agency director or medical director of an agency.

"Distribution." The shipment and delivery of allografts for recipient use.

"Donation." The free and voluntary gift of one or more organs or tissues for the purpose of medical research or transplant surgery.

"Donor." A medically acceptable person where appropriate informed consents and permissions have been obtained to procure organs or tissues, or both, in accordance with 20 Pa.C.S. Ch. 86 (relating to anatomical gifts).

"Eye." The sense organ for sight that is composed of three major layers, the corneo-sclera, uvea and retina, their intraocular contents and the surrounding conjunctiva, muscles and optic nerve.

"Eye bank." A public or private entity which demonstrates proficiency in all aspects of eye banking, including procuring, processing and distributing corneas for penetrating keratoplasty.

"Facilities." Any area used for procurement, processing, testing, storage or distribution of organs, tissues and tissue components.

"Graft." A piece of skin, bone or other tissue to be transplanted to another place on the human body.

"Indirect supervision." The direction provided to coordinators and other staff under the protocols expressly approved by the agency's medical director. The medical director or his designee shall always be available, in person or by telephone, to provide medical direction and consultation.

"Informed consent." Permission to procure an organ or tissue, or both, from living or nonliving donors which is obtained only under circumstances that provide the prospective donor or donor's next of kin sufficient opportunity to consider whether or not to agree to donation and that minimize the

possibility of coercion or undue influence.

"Label." Written, printed or graphic matter on the container or package or any such matter clearly visible through the immediate carton, receptacle or wrapper.

"Lessee." A person who contracts with another person to occupy or use space to serve as an agency.

"License." A license to operate as an organ procurement organization, tissue bank or eye bank which is issued by the Department of Health to those agencies which meet and maintain compliance with this act.

"Licensee." A person issued a provisional license or license by the Department of Health to operate an agency.

"Moratorium." An immediate suspension of activity.

"Next of kin." The person or persons most closely related to a deceased individual as designated by applicable law.

"Organ." A body part such as a heart, kidneys, pancreas, liver, lungs or intestines that requires vascular reanastomosis other than bone.

"Organ procurement organization" or "OPO." A public or private nonprofit entity which is registered as nonprofit with the Department of State and designated as an organ procurement organization by the Secretary of the United States Department of Health and Human Services.

"Package." The immediate carton, receptacle or wrapper, including all labeling matter therein and thereon, and the contents of the one or more enclosed containers.

"Person." A natural person, partnership, association, joint venture, trust, governmental entity, corporation, health facility, organ procurement organization, tissue bank, eye bank or any other entity.

"Preservation." The proper combination of conditions that serve to protect organs, tissues and eyes from decay during established periods.

"Procedure." A series of activities followed in a regular and definite order.

"Processing." The procedure employed after organ, tissue and eye procurement and before storage of the final container material. The term includes identification of the organ or tissue, organ and tissue treatment, preparation of components from the organ and tissue, testing, labeling and associated recordkeeping.

"Procure." The removal of organs, tissues or eyes for the benefit of one or more patients for transplantation or medical research.

"Procurement." The retrieval, processing and distribution of organs, tissues or eyes.

"Quality assurance." The monitoring procedures that ensure and document that the entire agency including, but not limited to, facilities, personnel, methods, practices and records, conforms with these standards.

"Quality control." Laboratory tests and procedures for measuring or monitoring properties of organs and tissues essential to the evaluation of their safety or usefulness.

"Revocation." The removing of an agency's license to operate in this Commonwealth.

"Sensitizing agents." Any foreign substance capable of inducing a state of altered reactivity in which the recipient reacts with an immediate or delayed exaggerated response when reexposed to the foreign agent.

"Storage." The proper combination of conditions that serve

to protect organs and tissues during established periods.

"Suspension." The temporary cessation of licensed function or activity.

"Tissue." Any nonvisceral collection of human cells and their associated intercellular substances.

"Tissue bank." A public or private entity involved in procuring, processing, storing or distributing viable or nonviable human tissues for purposes of transplantation or research.

"Transplant safety." The assurance of relative freedom from harmful effect to persons affected, directly or indirectly, by a transplant when administered, taking into consideration the character of the transplant in relation to the condition of the recipient at the time.

"Transplant surgeon." A licensed practitioner who performs surgical repair or replacement using organs or tissues donated by a living or nonliving donor.

CHAPTER 3

LICENSURE AND GENERAL STANDARDS

Section 301. Licensure procedure.

(a) General rule.--No person shall establish, operate or maintain an OPO, tissue bank or eye bank or any operation similar in activity thereto in this Commonwealth without first being certified and licensed to operate by the department.

(b) Certain dentists and physicians.--A dentist or physician using tissue processed by a licensed tissue bank, but who is not involved in the procurement, processing and distribution of tissue, is not required to be certified or licensed pursuant to this act.

(c) Submission of application.--All persons contemplating

the operation of an OPO, tissue bank or eye bank or anything similar thereto shall complete and submit to the department a completed application, furnished by the department, and a statement, signed by the chief executive officer, that the agency shall comply with this act and other applicable State laws.

(d) Site inspection.--Upon receipt of a completed application from the applicant, the department shall conduct a site inspection within 180 days to determine agency compliance with the standards under this act.

(e) License issuance.--Agencies found in compliance with the standards applicable to the applicant shall be issued a license by the department. Each license shall specifically state the license number, name of the agency, agency owner, city and county location of the agency, type of agency, issue date of the license and expiration date of the license. A person having more than one agency shall be issued a separate license for each agency. A license shall be posted in a conspicuous place on the licensed premises and copies of licenses shall be made available for inspection to all individuals.

(f) Expiration.--A license, unless sooner suspended or revoked, shall automatically expire two years from date of issuance and shall be renewable biennially upon application in accordance with subsection (c) if the agency has complied with Chapters 13 and 15 during the previous licensing period and it currently complies with the standards as determined by a site inspection under subsection (d).

(g) Name.--Each agency for which a license is requested shall be designated by a distinctive name, and the name shall not be changed without first notifying the department and

receiving approval in writing. Duplication of existing agency names is prohibited.

(h) Validity of license.--Each license shall be valid only for the person to whom it is issued and shall not be subject to sale, assignment or other transfer, voluntary or involuntary, nor shall a license be valid for any premises other than that for which it was originally issued.

(i) Transfer of license.--An application for a license is required when the ownership of a licensed agency has been transferred or assigned or when a lessee agrees to undertake or provide services to the extent that legal liability for operation of the agency rests with the lessee. The application for a license reflecting this change shall be made at least 60 days prior to the date of the sale, transfer, assignment or lease.

(j) Return of license.--Each license shall be returned to the department by the agency immediately upon change in ownership or classification, suspension, revocation or voluntary cessation of operations.

(k) Notification of agency closure.--A licensee shall notify the department of impending closure of an agency 90 days prior to the closure. The agency shall be responsible for advising the department as to the placement of inventory and disposition of records.

(l) Provisional license.--Agencies in existence on the effective date of this act shall receive provisional licensure by submitting a letter of intent to continue operation as an agency, together with an audited financial statement for the most recently completed annual or fiscal year. Provisional licenses shall expire at the time that a license is issued.

Section 302. Organizational requirements.

(a) Institutional identity.--The purposes of the agency shall be clearly established and documented. Whether it is an independent agency or part of another institution shall also be defined. The agency shall have a functional identity with a professional staff and a commitment to maintain and preserve records and operating procedures for future reference and historical continuity.

(b) Board of directors or advisory board.--Each agency shall have a board of directors or an advisory board which provides consultation and direction on all policymaking decisions as well as issues of liability, fiduciary responsibility and selection of the agency director. Where the agency operates within the jurisdiction of an educational institution, the responsibilities of this board shall not conflict with the responsibilities or span of control of the authorized administrator of the agency.

(c) Agency director.--

(1) All procedures and policies shall be developed and maintained under the supervision of an agency director appointed by the board of directors or advisory board or in the case of an educational institution, the authorized administrator of the agency. This person shall be qualified by training or experience for the scope of activities being pursued.

(2) The agency director shall be responsible for all administrative operations, including, but not limited to, compliance with these standards. If the agency director appointed does not have medical licensure, the agency shall have a licensed physician under contract to ensure compliance with all medical-legal aspects and with all requirements for

specialist knowledge of the particular organs and tissues processed or infectious disease.

(3) The agency director shall be the individual responsible for the daily operation of the agency. It is this person's responsibility to carry out policies of the board of directors or advisory board and to prescribe technically acceptable means for procuring, processing, quality control, storage and distribution.

(4) The agency director shall provide all staff members with adequate information to perform their duties safely and competently.

(5) The agency director shall be responsible for ensuring that technical staff maintain competency by participation in training courses and technical meetings or other educational programs. This training should be recorded in each employee's personnel file. Delegation of responsibility for technical work, recordkeeping and administration may be made.

(6) To ensure quality control, the agency director shall ensure tests and procedures for measuring, assaying or monitoring properties of organs and tissues essential to the evaluation of their safety and usefulness are carried out. Results of all tests or procedures, together with evaluations based on these findings, shall become part of the permanent record of all material processed.

(7) To ensure quality assurance, the agency director shall establish monitoring and recording procedures that ensure and document that the entire agency is in conformity with applicable Federal and State standards. These procedures and records shall be reviewed at least annually.

(8) The agency director shall appoint technical staff and be responsible for ensuring that staff have capabilities and training appropriate to their function. Qualifications in some cases may be demonstrated by certification or by examination through recognized specialty organizations.

(d) Medical director.--Each OPO, tissue bank and eye bank shall employ or have under contract a Commonwealth licensed physician medical director who provides direction and supervision to coordinators and all other nonphysician staff who assist in the procurement of organs, tissues or eyes for transplantation or research. This may be by indirect supervision.

(e) Personnel policies and procedures.--Job descriptions, including scope of activities, specific responsibilities and reporting relationships, for all personnel shall be established by written personnel policies and procedures approved by the agency director and the board of directors.

(f) Policies and procedure manual.--

(1) Each agency shall maintain a policies and procedures manual which details all aspects or procurement, processing, testing, storage and distribution practices.

(2) Each of these procedures shall be reviewed and affirmed in writing annually by the agency director or designee. Modifications of standard procedures and development of new procedures shall be approved by the agency director or designee.

(3) Obsolete revised procedures shall be retained separately to maintain a historical sequence.

(4) Copies of the policies and procedures manual shall be available to the staff at all times. Staff shall be

required to affirm in writing in the manual to signify that they have read and understand the manual.

(5) Copies of procedures from published literature cited by reference shall be attached in an appendix to the policies and procedures manual.

(6) Copies of the policies and procedures manual shall be restricted to authorized individuals, including administration employees, for inspection upon request.

(7) Procedures shall be sufficiently detailed and unambiguous to allow an appropriately trained individual to follow and complete the procedure successfully.

(g) Records.--

(1) Donor and recipient records shall be confidential, accurate and complete. Donor record confidentiality shall not preclude access to pertinent information by authorized employees of the department and the medical examiner or coroner for cases which fall within his jurisdiction. Donor medical records and results of all laboratory tests shall be reviewed by the medical director, designees or appointee to ensure suitability of the donated organ, tissue or eye for the intended application.

(2) Documentation shall be concurrent with the performance of each activity in the procurement, preparation, testing, storage and distribution of organs, tissue and eyes in such a manner that all activities can be clearly traced. All records shall be legible and indelible, shall identify the person performing the procedures or tasks, include dates of entries and record test results and the interpretation of the results. The expiration date assigned to specific processed tissues where appropriate is to be recorded.

(3) Records shall be as detailed as necessary for a clear understanding of each activity by an experienced person and shall be available for inspection by authorized individuals, including administration employees, upon request and within the bounds of medical-legal confidentiality.

(4) Each organ and tissue and any components derived therefrom shall be assigned, in addition to generic designation, one unique identification number which shall serve as a lot number to identify the material from procurement through distribution and utilization.

(5) Records shall identify the donor, document the pathological evaluation or microbiological evaluation or both of the donor, verify laboratory conditions under which the organ or tissue is procured, processed, tested and stored and indicate disposition of the transplanted organ, tissue or eye. These records shall be maintained, reviewed and approved by the agency director or designee. All records concerning donor history and processing information shall be made available to the transplant surgeon upon request, except those infringing upon donor confidentiality.

(6) All records and communication between the agency and its donors and patient recipients shall be regarded as confidential and privileged. The department shall have access with adequate notice.

(7) Maintenance records on facilities, instruments and equipment, including their monitors, shall be maintained.

(8) An adverse reactions file shall be maintained pursuant to section 315.

(9) All of these records shall be retained for at least ten years after distribution of organs or tissues.

Section 303. Physician supervision of cadaveric organ, tissue and eye procurement coordinators.

Organ procurement organizations, tissue banks and eye banks may employ coordinators to assist in the medical management of organ donors or in the surgical procurement of cadaveric organs, tissues or eyes for transplantation or research under the direction and supervision of a licensed physician. This supervision may be indirect supervision.

Section 304. Safety and environmental control.

(a) Procedures in general.--Written procedures for the operation of the agency shall be established and approved by the agency director and include instructions for action in case of emergency or exposure to communicable disease and chemical, biological and radiological hazard precautions.

(b) Disposal procedure.--Human waste items shall be disposed so as to minimize any hazard to personnel or the environment. Dignified and proper disposal procedures shall be used to obviate recognizable human remains.

(c) Compliance with OSHA rules.--Each agency shall comply with Occupational Safety and Health Administration (OSHA) rules, including 29 CFR 1910.1030 (relating to bloodborne pathogens). These rules establish requirements for minimizing exposure to hepatitis, HIV and other bloodborne pathogens.

Section 305. Facilities and equipment.

Facilities shall be designated for the specialized purposes for which they are to be used and shall be maintained in a clean and orderly manner. All instruments and equipment shall be subject to regularly scheduled maintenance and calibration. Refrigerators and freezers for storage shall have alarms and back-up systems in case of failure and shall be inspected on a

regularly scheduled basis as described in the equipment's operating manual and equipped with verifiable methods for proper temperature monitoring. Access shall be limited to authorized agency and administration employees. An adequate security system of physical configuration shall be provided to prevent entry of unauthorized persons.

Section 306. Ethical standards.

Each OPO, tissue bank and eye bank shall establish policies to avoid conflicts of interest.

Section 307. Educational standards.

The following documentation and information is required:

(1) Each OPO, tissue bank and eye bank shall maintain documentation of educational services provided to citizens and hospitals in the areas the agencies service.

(2) Documentation of education of professionals shall be maintained. Documentation of donor hospital policies, procedures, characteristics and donor-related activities shall be kept as indicated. Written agreements shall document these activities.

(3) Each agency shall produce or have available literature that will provide education for donation of organs, tissues or eyes. Each agency shall be responsible for establishing or assisting in the dissemination of these materials.

(4) Each agency shall provide documentation of educational programs given to the citizens, directly or indirectly.

Section 308. Agency investigations.

Each agency shall provide to the department, upon request, a copy of any audit, review or study performed by any Federal or

accreditation organization that has or is reviewing that agency.

Section 309. Acquisition of organs and tissue.

(a) General rule.--

(1) The most sensitive relationship between an OPO, tissue bank or eye bank and the community concerns the process whereby material from recently deceased or living donors is obtained. Procedures adopted for recruiting donors shall be fully discussed with the board of directors, advisory board or appropriate officials.

(2) Agency personnel shall ensure that consent for donation is obtained in compliance with applicable Federal, State and local laws.

(3) Agency personnel shall be trained regarding obtaining and documenting consent for donation.

(4) Consent shall be obtained from the donor, next of kin or other designated legal entity in order of priority and availability in accordance with 20 Pa.C.S. Ch. 86 (relating to anatomical gifts).

(5) In cases originating in a hospital, the consent form shall remain a part of the patient's hospital medical record.

(6) A copy of the consent form must be retained in the agency's donor record.

(b) Informed consent.--

(1) Permission to obtain organs or tissue from living or nonliving donors by informed consent shall be documented. Information provided shall be written or spoken in language understandable to the donor or the donor's next of kin.

(2) Permission to procure organs or tissue from nonliving donors shall be sought as provided in 20 Pa.C.S. Ch. 86.

Section 310. Premortem donations.

Instructions expressed by a living person to donate organs, tissues or eyes under 20 Pa.C.S. Ch. 86 (relating to anatomical gifts), either through use of donor cards, living will or other appropriate documents are legally valid and enable organ procurement organizations, tissue banks and eye banks to procure organs and tissue without further authorization from next of kin. It is recommended that the next of kin be informed and their cooperation secured.

Section 311. Compensation for donors.

Monetary compensation other than reimbursement of donation-related expenses or Federal or State-approved donor compensation programs made to living donors, next of kin, donor's estate or any other third party is prohibited.

Section 312. Sale of anatomical matter.

Sale of one of a pair of organs, such as an eye or kidney, by a living donor for financial compensation is illegal under the act of December 18, 1984 (P.L.1064, No.210), entitled "An act prohibiting the transfer of certain human organs and tissues for valuable consideration." A licensed agency involved in this activity shall be subject to revocation of that license.

Section 313. Donor selection.

The following shall apply:

(1) Suitability of a specific individual for organ or tissue donation shall be based upon the medical history and clinical status of the donor and the need for particular organs or tissue.

(2) Criteria for evaluating a potential donor shall include presence of infectious disease, malignant disease, neurological degenerative disease and diseases of unknown

etiology. In equivocal situations, a specialist in the particular area of medicine should be consulted.

(3) A thorough examination of the prospective donor's available medical records is required. If no medical records are available, an autopsy or generally accepted testing is required. Evaluation of the record shall be performed by an agency designee.

(4) Social and additional medical history of the donor, if available, shall be obtained by means of discussion with the family, donors' personal physician or other individual. The United States Public Health Service criteria shall be considered in the evaluation of high risk donors. Applicable published Federal regulations shall also apply.

(5) Appropriate policy distinctions shall be made regarding acceptability of organs and tissue from living donors. In general, donations from living donors shall not be accepted if the conditions surrounding the donations are questionable. These conditions range from undue medical risk to the donor, coercion and promises of monetary gain, to diminished capacity of the donor to evaluate the medical or surgical risks to be undertaken.

(6) The agency shall have the responsibility to document in writing the current medical history, physical examination and inspection and laboratory test results, together with the available previous medical and social history of the donor.

Section 314. Reconstruction.

Each agency shall have a policy for the reconstruction of the body which is integral to maintaining the dignity of the donor.

Section 315. Report of adverse reactions.

(a) General rule.--It is the responsibility of each

physician or organization that utilizes organs and tissues for transplantation to notify the providing organ procurement organization, tissue bank or eye bank of any and all adverse reactions. The providing organization shall notify the medical examiner or coroner if the adverse reaction involves donation from a medical examiner's or coroner's case. Every reasonable effort shall be made by each providing agency to inform each receiving agency or physician of this fact and to provide a mechanism for a follow-up report in these instances. Upon notification of an adverse reaction, the procurement agency shall:

(1) Immediately notify the department by telephone of the reporting of an adverse reaction.

(2) Immediately suspend distribution of grafts procured from that donor.

(3) Initiate an investigation to determine whether the adverse reaction was due to the donor's organ or tissue.

(4) Submit to the department within two working days, an adverse reaction reporting form to be furnished to the agency by the department.

(b) Procedures.--If it is determined that the adverse reaction was due to the donor's organ or tissue, the recall procedures described in section 316 and the look-back procedures described in section 317 shall be implemented immediately. When the cause of the adverse reaction is determined, the procurement agency shall submit to the department on a form provided by the department information related to probable cause and the basis for this determination. Documentation of adverse reaction procedures shall be included in the agency's policies and procedures manual.

Section 316. Recall procedures.

A written procedure shall exist for recall of organs and tissues and for notification to recipients for the possibility of infection, disease or contamination, defects in processing, preparation or distribution or other factors affecting suitability of the organs or tissues for their intended application. Documentation of recall procedures shall be included in the agency's policies and procedures manual.

Section 317. Look-back procedures.

Each OPO, tissue bank and eye bank shall have procedures for notifying the transplanting agency or physician that they may have received infected, diseased or otherwise unsuitable transplants. These notification or look-back procedures would enable those at risk for a disease to be tested and if necessary enter treatment. This would also potentially prevent further transmission of infection or other disease. Documentation of look-back procedures shall be included in the agency's policies and procedures manual.

Section 318. HIV notification requirements.

Testing and notification of HIV (human immunodeficiency virus) test results to donors and recipients of organs, tissues and eyes in this Commonwealth shall be in accordance with the act of November 29, 1990 (P.L.585, No.148), known as the Confidentiality of HIV-Related Information Act.

Section 319. Data collection.

Each organ procurement organization, tissue bank and eye bank shall collect, maintain and report the following data annually to the department:

(1) Number of donors by age and race.

(2) Type of donation.

(3) Manner of death for all donors.

(4) Donor source (hospital, medical examiner, coroner or funeral home).

(5) Number of organs, tissues and eyes procured.

(6) Number of organs, allografts and eyes processed.

(7) Disposition of locally procured or processed organs, tissues and eyes with respect to international, national, in-State or local distribution.

(8) Revenues derived from procuring, processing and distribution of organs, tissues and eyes.

Section 320. Federal, State and local laws.

Commonwealth organ procurement organizations, tissue banks and eye banks shall comply with all applicable Federal, State and local government laws and regulations.

Section 321. Revision of standards.

All proposed revisions, additions and deletions shall be reviewed for acceptance or rejection at least annually by the Organ Tissue Procurement and Transplantation Advisory Board's Standards subcommittee. Recommendations from the Standards subcommittee shall be reviewed by the advisory board and subsequently submitted to the department for consideration and appropriate action.

CHAPTER 5

ORGAN PROCUREMENT ORGANIZATION STANDARDS

Section 501. Organizational requirements.

(a) General rule.--Each OPO shall:

(1) Be a nonprofit entity that is exempt from Federal income taxation under section 501(c)(3) of the Internal Revenue Code of 1986 (Public Law 99-514, 26 U.S.C. § 1 et seq.).

(2) Have accounting and other fiscal procedures necessary to assure the fiscal stability of the organization, including procedures to obtain payment for kidneys and nonrenal organs provided to transplant centers.

(3) Have an agreement with the Secretary of the United States Department of Health and Human Services to be reimbursed under Title XVIII of the Social Security Act (49 Stat. 620, 42 U.S.C. § 301 et seq.) for the procurement of kidneys.

(4) Make available to the department documentation of its service area. An OPO must provide to the department quantifiable data showing that the area is of sufficient size to assure maximum effectiveness in the procurement and equitable distribution of organs and that either includes an entire metropolitan statistical area, as specified by the Director of the United States Office of Management and Budget, or does not include any part of such an area. Documentation that precisely defines the proposed service area includes the following:

(i) the names of the counties served;

(ii) geographic boundaries of the service area for which the United States population statistics are available;

(iii) total population in service area; and

(iv) the number of and the names of acute care hospitals in the service area with an operating room and the equipment and personnel to procure organs.

(b) Board of directors or advisory board.--The OPO shall have a board of directors or advisory board that has the authority to establish policies relating to the donation,

procurement and distribution of organs. The OPO shall have a board of directors or an advisory board which provides consultation and direction on all policymaking decisions as well as issues of liability, fiduciary responsibility and selection of the agency director. Where the agency operates within the jurisdiction of an educational institution, the responsibilities of this board should not conflict with the responsibilities or span of control of the authorized administrator of the agency. The board of directors or advisory board shall include members as provided under the National Organ Transplant Act of 1984 (Public Law 98-507, 42 U.S.C. § 273 et seq.) and adhere to applicable Federal and State law.

(c) Staff.--Each OPO shall:

(1) Have an agency director, as described in section 302, and such other staff, including an organ donation coordinator and an organ procurement specialist, necessary to obtain organs effectively from donors in its service area.

(2) Employ or have under contract a Commonwealth licensed physician medical director, as described in section 302, who provides indirect supervision to coordinators and all other staff who assist in the medical management of donors and recovery of organs for transplantation or research.

(d) Staff qualifications.--Qualifications of technical personnel vary by nature of responsibility. Qualifications, in some cases, may be demonstrated by certification or by examination through recognized specialty organizations. All supervisory or senior OPO personnel shall be certified in organ procurement by the North American Transplant Coordinators Organization or by a State agency.

Section 502. Operational procedures.

(a) Identification of donors.--The OPO shall have documented evidence for identification of potential donors which includes:

(1) Having a working relationship with at least 75% of the hospitals that participate in the Medicare and Medicaid programs in its service area that have an operating room and the equipment and personnel for procuring organs.

(2) Having a working relationship with medical examiner or coroner offices in the service area.

(3) Conducting systematic efforts intended to acquire all suitable organs, tissues and eyes for transplantation from potential donors.

(b) Cooperative arrangements.--The OPO shall:

(1) Arrange for the appropriate tissue typing of donated organs.

(2) Provide or arrange for the transportation of donated organs to transplant centers.

(3) Have arrangements to coordinate its activities with transplant centers in the area.

(4) Have arrangements to cooperate with licensed tissue banks and eye banks for the procurement, processing, preservation, storage and distribution of tissues and eyes as may be appropriate to assure that all usable tissues and eyes are obtained from potential donors.

Section 503. Records.

The OPO shall maintain data in a format that can be readily used by a successor OPO and agree to turn over to the department and to the Secretary of the United States Department of Health and Human Services copies of all records and data necessary to assure uninterrupted service by a successor OPO. The OPO shall

have a procedure for ensuring the confidentiality of patient records. Information from or copies of records shall be restricted to appropriate staff, the medical examiner or coroner and authorized department employees. The OPO shall ensure that unauthorized individuals cannot gain access to or alter patient records. Original medical records may be released by the OPO only in accordance with applicable Federal or State laws, court orders or subpoenas.

Section 504. Organ Procurement and Transplantation Network (OPTN).

The OPO shall participate in the OPTN and adhere to its rules.

Section 505. Community involvement and education.

The OPO shall assist hospitals in establishing and implementing protocols for making routine inquiries about potential donors. The OPO shall conduct and participate in education concerning donation for professionals and laypeople. The OPO shall aid the department in the evaluation of the effectiveness of the agency in acquiring potential donors' organs.

Section 506. Quality assurance.

(a) General rule.--Each OPO shall have an established and documented quality assurance program. This program shall include ongoing monitoring and evaluation of its activities. These standards shall provide the basis for development of the quality assurance program. Each OPO shall document all aspects of its quality assurance program and maintain records of all quality assurance activities for a minimum of ten years.

(b) Reporting of adverse reactions.--The OPO's quality assurance program shall include a method for the transplanting

surgeon to report adverse reactions from the transplantation of an organ to the source OPO which, in turn, shall forward the adverse reaction information to the department as prescribed in section 302.

Section 507. Performance standards.

The OPO shall meet performance standards under the National Organ Transplant Act of 1984 (Public Law 98-507, 42 U.S.C. § 273 et seq.) and adhere to applicable Federal and State law.

Section 508. Financial policies and procedures.

(a) General rule.--The OPO shall comply with existing Federal laws and guidelines in its fiscal and accounting procedures. The OPO shall have accounting and other fiscal procedures necessary to insure the fiscal stability of the OPO, including procedures to obtain payment for kidneys and nonrenal organs provided to transplant centers. The following are required:

(1) There shall be an annual budget approved by the board of directors or advisory board.

(2) Unless otherwise provided by law, there shall be an annual audit conducted by an independent public accountant.

(3) There shall be adequate trained staff or qualified contractors to ensure the establishment and maintenance of internal controls and general accounting functions. The general accounting functions shall include management of accounts receivable, management of accounts payable and other disbursements and the handling of cash. An OPO shall maintain the ability to generate periodic statements of the status of the agency's assets, liabilities and fund balance and statements of its periodic revenues and expenses.

(b) Documentation of costs.--The OPO shall have policies and

procedures established for the documentation of all direct and indirect costs. These costs shall be used as the basis for the establishment of organ and tissue procurement charges.

(c) Allocation of costs.--An OPO shall establish accounting policies and procedures to permit allocation of all its direct and indirect costs to the organ and tissue cost centers maintained by the agency. The policies and procedures shall be in compliance with the current approved Medicare cost report (HCFA-216).

(d) Records of allocations.--The accounting records of the OPO shall include documentation of allocations made to organ and tissue cost centers, as applicable, for each direct expense incurred by the OPO. Allocations shall be made insofar as they are related to the procurement of the particular organ. For example, records documenting the payment of a donor hospital bill shall identify the procured organs of the particular case and shall document the equal allocation of the costs to each organ type. The same procedure shall apply to other direct expenses related to the procurement, such as tissue typing or transportation. When these expenses are for the purpose of procurement of a particular organ, the cost shall be allocated only to that organ.

(e) Accounting of indirect costs.--The accounting records of the OPO shall permit the expensing of indirect costs. For example, office rent, utilities, administrative salaries, salary-related costs and other expenses may be allocated in compliance with Medicare rules and guidelines. The OPO's costs shall be charged as expenses and allocated in accordance with the appropriate guidance provided by the Medicare program or by established agreements with other agencies, companies, providers

or vendors. The costs paid by the OPO for services used in the procurement of organs, for example, surgeon's fees, donor evaluation fees, laboratory and transportation costs shall be based on reasonable and customary fees within the service areas as determined by the OPO. The OPO may refer to limitations on the reimbursement of such costs as specified by the Medicare program. The OPO shall exercise judgment and prudent management practices in the determination of payment of such fees.

(f) Acquisition charges.--The OPO shall maintain the ability to develop and utilize average procurement costs as a basis for establishment of its organ and tissue acquisition charges. The acquisition charges are to be established in accordance with the OPO's board of directors or advisory board and with reference to prevailing Medicare program rules and regulations. These charges shall be reviewed at least semiannually and appropriate adjustments made unless otherwise proscribed.

Section 509. Verification of death.

Where applicable, the OPO shall assure that death has been determined in accordance with the act of December 17, 1982 (P.L.1401, No.323), known as the Uniform Determination of Death Act, and documented in the organ donor's medical record.

Section 510. Autopsy.

A gross external and internal examination of any area of the donor altered by the excision shall be performed and dictated or otherwise recorded by the excising surgeon at the time of the surgical removal of organs from the cadaveric donor. A written report of these findings shall be timely prepared and delivered to the person responsible for the autopsy if performed on the donor. The report shall contain an itemization of all normal conditions noted as well as all abnormal pathological findings

found during the gross internal examination of the donor. Whenever a full medical autopsy of the donor will not subsequently be performed by a medical examiner or coroner, the OPO may attempt to obtain a medical autopsy. Upon request, the OPO shall make a copy of the autopsy report, including any preliminary findings, available to all agencies which are in receipt of the donor's organs, tissues or eyes and will fix a copy of the report in the OPO's donor record.

Section 511. Guidelines for the evaluation and management of a potential cadaveric organ donor.

(a) General rule.--Evaluation and management of donors is mandatory for organs which may be allocated to and received by the Organ Procurement and Transplant Network (OPTN) approved transplant programs to assure that all organ donors meet the requirements established by the OPTN. The OPO's organ donor evaluation and management procedures shall be approved by the OPO medical director or the OPO medical advisory committee or its equivalent, or both. These procedures are to be undertaken with direct or indirect medical supervision and support as necessary. Once the patient has been declared dead or death is imminent and consent for donation has been obtained as authorized by law, the OPO shall implement the guidelines for the evaluation and management of the potential organ donor.

(b) Evaluation criteria.--The evaluation of the donor shall include:

(1) An attempt to acquire a social history which may be obtained from individuals not limited to the person giving consent.

(2) A physical examination of the donor.

(3) Documentation of the donor's ABO group, donor's

weight and height.

(4) A review of the donor's current inpatient medical record.

(5) Documentation of significant events in the donor's clinical course.

(c) Other requirements.--The OPO shall ensure that adequate respiratory, hemodynamic and electrolyte management of the donor is provided. The OPO shall ensure that the donor receives appropriate antibiotic coverage, if a need is indicated.

(d) Evaluation of infectious disease status.--The OPO shall evaluate the infectious disease status of the potential donor. All serological testing shall be noted to be either pretransfusion or posttransfusion. Such evaluation shall include serology testing in accordance with applicable Federal law.

(e) Tissue typing requirements.--For those organ systems for which the OPO assumes responsibility for tissue typing, the OPO shall ensure that tissue typing is performed by an affiliated American Society of Histocompatibility and Immunogenetics (ASHI) and Organ Procurement and Transplant Network (OPTN) approved and Commonwealth-licensed histocompatibility laboratory and tissue typing material is provided to the laboratory for testing.

Section 512. Allocation of donated organs.

Each OPO shall have a policy to ensure that donated organs are allocated according to the standards of the Organ Procurement and Transplant Network (OPTN) and in keeping with OPTN-approved local variances. Organs that are allocated outside of the sequence of patients, as determined by the OPTN, shall have documentation explaining the reason for the variance. The OPO shall run the OPTN computer for a donor/recipient match routine on every donor organ procured by the OPO. Organs shall

be allocated by the OPO utilizing the sequence of patients as determined by OPTN computer. Any variation from the OPTN donor/recipient match routine shall be documented and become a permanent part of the donor record. Documentation of actual allocation of each organ procured shall be filed in accordance with OPTN guidelines.

Section 513. Procurement procedures.

(a) General rule.--The OPO shall have policies and procedures to facilitate and coordinate the procurement of donated organs by trained and qualified personnel.

(b) Surgical standards.--The OPO shall ensure that any surgeons working as consultants to the OPO for the procurement of donated organs, that is, surgeons whose fees are paid by the OPO, meet qualifications and standards as set by the OPO medical director or its medical advisory committee or its equivalent, or both. Any surgeon who procures organs for an OPO and is not working as a consultant to the OPO, that is, a surgeon working for a specific transplant center, must be employed by an OPTN approved transplant center. The transplant center, not the procuring OPO, shall be responsible for assuring the qualifications of the procuring surgeon. The medical director of the OPO shall be responsible for periodically reviewing the surgical standards and technical quality of services provided by consulting surgeons. The OPO is responsible for coordinating anesthesia support for the organ procurement process. The OPO shall provide information and guidelines to anesthesia for the intraoperative procedure. The goal of this intraoperative support includes:

(1) Maintaining an adequate blood pressure, fluid volume, organ perfusion and function.

(2) Adequate oxygenation and oxygen transport to the organs being procured.

(3) Replacement of excessive volume loss.

(4) Administration of required and desirable medications to facilitate organ procurement and function.

(c) Packaging and labeling.--The OPO is responsible for packaging and labeling organs, tissue typing material and blood, according to the OPTN standards.

(d) Documentation to transplant center.--The OPO is responsible for distributing the following documentation to each transplant center receiving an organ from an individual donor:

(1) Verification of donor ABO type.

(2) A copy of death determination from the donor's medical record.

(3) A copy of consent for organ procurement from the donor's medical record.

(4) A copy of the OPO donor information as described in section 514.

Section 514. Documentation of donor information.

(a) Demographic information.--The OPO shall be responsible for documentation of demographic information relative to the donor so that pertinent information is available for centers considering organs for transplant. The OPO shall document information that will enable follow-up with the next of kin and donor hospital personnel.

(b) Required information.--The OPO shall have a standardized method of recording the following information on each donor:

(1) Name.

(2) Age, sex and race.

(3) Cause of death.

(4) Time and date of hospital admission.

(5) Time and date of pronouncement of death.

(6) UNOS identification number.

(7) OPO identification number.

(c) Follow-up information required.--The OPO shall document the following information for purposes of a follow-up:

(1) Name and address of the legal next of kin.

(2) Record of the organs donated.

(3) Name of attending and consulting doctor.

(4) Medical examiner or coroner, as applicable.

(5) A copy of signed consent form.

(6) A copy of declaration of death note.

(d) Documentation of donor history.--The OPO shall obtain a current medical and social history of each potential donor in an attempt to determine whether the potential donor is in a high risk group as described in section 313. That history shall be communicated in writing to the recipient institution.

(e) Specific episodes to be reported.--The documented past medical history shall, when available, include significant episodes of the following:

(1) Any previous hospitalization.

(2) Any prior surgery.

(3) History of a chronic illness, for example, diabetes, hypertension and cardiovascular disease.

(4) History of communicable disease, for example, hepatitis.

(5) History of disease specific to transplantable organs and treatment of same.

(f) Current hospital history.--The current hospital history as the most vital shall include:

(1) A description of injuries and treatments, that is, surgeries.

(2) An account of significant febrile episodes, including duration, treatment and response.

(3) An account of cardiac or respiratory arrests, including type, duration and treatment required to restore function, particularly closed-chest massage.

(4) A record of blood transfusions, including type and amount.

(g) Documentation of donor hemodynamics.--The OPO shall document a detailed picture of the donor's hemodynamic status from admission through organ procurement in a standardized, easy to interpret manner.

(h) Transfused donor.--All potential donors are to be tested by a United States Food and Drug Administration licensed screening test for HTLV-I and HIV-Ab 1 and 2. If the donor's pretransfusion test is antibody negative and subsequent transfusions are pretested, retesting for HTLV-I and HIV-Ab 1 and 2 is not necessary. If no pretransfusion blood sample is available, the donor institution must provide, along with the screening test results, a complete history of all transfusions received by the donor during the ten-day period immediately prior to removal of the organs. The transplant surgeon is obligated to notify the recipient or next of kin in such cases prior to transplantation when the result of a test administered under this subsection is positive. The OPO shall notify the donor's attending physician who is obligated to notify the donor's next of kin in such cases when the result of a test administered under this subsection is positive.

Section 515. Documentation of organ-specific laboratory

results.

The OPO shall provide the transplanting physician with a completed agency donor record.

Section 516. Documentation of recipient information.

(a) General rule.--The OPO shall document specific information on the recipients of procured organs.

(b) Specific information to be documented.--The following information shall be documented on each recipient:

(1) Name.

(2) Health insurance claim number.

(3) Recipient center.

(4) Age, sex and race.

(5) Organ function at time of transplant.

(6) Any other information required by OPTN.

Section 517. Completion of Organ Procurement and Transplant Network (OPTN) required forms.

Each OPO shall routinely submit documentation describing donor activity to OPTN. The OPO's shall comply with OPTN reporting requirements. All currently existing OPTN forms shall be completed by the OPO and submitted to the OPTN contractor within the prescribed time limits.

CHAPTER 7

TISSUE BANK STANDARDS

Section 701. Organizational requirements.

(a) General rule.--The purpose of the tissue bank shall be clearly established and documented. Whether it is an independent operation or part of another institution shall also be defined. The tissue bank shall have a functional identity with a professional staff and a commitment to maintain and preserve records and operating procedures for future reference and

historical continuity. Policy and procedure manuals shall be maintained for personnel and other agency activities.

(b) Board of directors or advisory board.--The tissue bank shall have a board of directors or an advisory board which provides consultation and direction on all policymaking decisions as well as issues of liability, fiduciary responsibility and selection of the agency director. Where the agency operates within the jurisdiction of an educational institution, the responsibilities of this board should not conflict with the responsibilities or span of control of the duly authorized administrator of the agency.

(c) Staff requirement.--Each tissue bank shall:

(1) Have an agency director as described under section 302 who shall:

(i) Be responsible for ensuring that technical staff maintain their competency by participation in training courses and technical meetings or other educational programs.

(ii) Establish in writing quality assurance procedures to monitor and record procedures which will ensure and document that the entire agency is in conformity with these standards. These procedures and records shall be reviewed yearly.

(2) Employ or have under contract a Commonwealth-licensed physician medical director as described under section 302 who provides indirect supervision to coordinators and all other staff who assist in the medical management of donors or in the surgical procurement of tissue for transplantation or research.

(d) Staff qualifications.--Qualifications of technical

personnel vary by nature of responsibility. Qualifications, in some cases, may be demonstrated by certification or by examination through recognized specialty organizations. All supervisory or senior personnel shall be certified in tissue banking by a recognized organization, such as the American Association of Tissue Banks or a State agency.

Section 702. Community involvement and education.

The tissue bank shall assist OPOs upon request in establishing and implementing protocols for making routine inquiries about tissue donations. The tissue bank may participate in education concerning tissue procurement for professionals and laypeople. The tissue bank shall aid the department in the evaluation of the effectiveness of the agency in acquiring potentially available tissue.

Section 703. Quality assurance.

(a) General rule.--Each tissue bank shall have an established and documented quality assurance program. This program shall include ongoing monitoring and evaluation of activities, identification of problems and development of plans for corrective action. These standards shall provide the basis for development of the quality assurance program. Each tissue bank shall document all aspects of its quality assurance program and maintain records of all quality assurance activities for a minimum of ten years.

(b) Reporting of adverse reactions.--The tissue bank's quality assurance program shall include a method for the transplanting surgeon to report adverse reactions from the transplantation of tissue to the source tissue bank, which in turn shall forward the adverse reaction information to the department as prescribed in section 302.

Section 704. Donor selection.

(a) Suitability of potential transplant donor.--Suitability of a specific individual for tissue donation shall be based upon the current medical and social history, clinical status of the donor and the condition of particular tissues. Consent must be obtained from the medical examiner or coroner, if appropriate.

(b) Criteria for rejecting potential transplant donors.--Criteria for rejecting a potential donor may be several and include presence of infectious disease, malignant disease, neurological degenerative disease and diseases of unknown etiology or any other diseases or conditions which may be transferred to the recipient.

(c) Medical testing information.--In selecting potential donors for procurement of tissues for transplantation, safeguarding the recipients from possible transmission of disease is of utmost importance. A medical history shall be examined, if available. However, in many instances of sudden death, a medical history is either scant or not available. In these cases a documented attempt shall be made to acquire information beyond what is immediately available in the donor's medical history before these tissues can be released. In the event that additional information or records cannot be found, the medical director shall determine if these tissues are suitable for release for transplantation and document their release in the donor's medical record.

(d) HIV infections.--Screening for elimination of individuals with human immunodeficiency virus (HIV) infections and HIV testing is required. Potential donors falling into United States Public Health Service high risk groups shall be eliminated from the donor pool.

(e) Conditions precluding tissue donation for transplantation.--Conditions which preclude donation of tissues are as provided under the United States Food and Drug Administration (FDA) emergency regulations of December 14, 1993, as well as any final FDA regulations promulgated thereafter.

Section 705. Required studies of donor.

The serologies required to be performed shall be as provided under the United States Food and Drug (FDA) emergency regulations of December 14, 1993, as well as any final FDA regulations promulgated thereafter.

Section 706. Evaluation of donor.

Prior to transplantation, the medical director, designees or medical contractee shall state in writing that the current medical history, postmortem examination and laboratory test results together with the available previous medical history are sufficient to indicate that the donor is acceptable for tissue transplantation.

Section 707. Microbiological examination.

Microbiological testing shall be performed by a Commonwealth-licensed laboratory which is also registered or certified under section 353 of the Public Health Service Act (58 Stat. 682, 42 U.S.C. § 263a). Each tissue bank or its consulting laboratory, in the event that the tissue bank uses such laboratory, shall have microbiological laboratory policies and procedures which assure allograft safety. Documentation of adherence to these policies and procedures is required.

Section 708. Tests performed on living donors.

Except with regard to bone marrow and other such critically viable transplants, tissues from living donors to be transplanted as allografts shall be held in quarantine for at

least 180 days after which time the donor shall be retested for HIV-Ab. This restriction shall not apply if and when the donor can be tested effectively for the presence of HIV antigen, viral DNA or other reliable indicators of early HIV infections by any of the United States Food and Drug Administration approved tests.

Section 709. Verification of death.

Where applicable, the tissue bank shall assure that death has been determined in accordance with the act of December 17, 1982 (P.L.1401, No.323), known as the Uniform Determination of Death Act, and documented in the donor's medical record.

Section 710. Autopsy.

A gross external and, if applicable, internal examination of any area of the donor altered by the procurement shall be performed and dictated or otherwise recorded by the procuring person at the time of the removal of tissues from the cadaveric donor. A written report of these findings shall be immediately prepared and delivered to the person responsible for the autopsy of the donor. The report shall contain an itemization of all normal conditions noted as well as all abnormal pathological findings found during the gross examination of the donor. Whenever a medical autopsy of the donor will not subsequently be performed by a medical examiner or coroner, the tissue bank may attempt to obtain an autopsy. The tissue bank shall affix a copy of the autopsy report to the donor record and, upon request, the tissue bank shall make a copy of the autopsy report available to all agencies which are in receipt of the donor's organs, tissues or eyes. The medical director or designees may exercise a waiver of an autopsy on a case by case basis and shall justify and document that waiver in the donor's medical record.

Section 711. Records.

(a) Type and inspection requirements.--Recordkeeping is of paramount importance in tissue banking efforts. Adequate records which identify the use of the allografts shall be maintained. The records of the tissue banks shall be open to inspection by the department at a mutually convenient time.

(b) Expiration dates.--Records shall show the expiration date assigned to specific processed tissues where appropriate.

(c) Additional guidelines.--Records shall be as detailed as necessary for a clear understanding of each step by a person experienced in tissue banking and shall be available for inspection by authorized individuals, including department employees, upon request and within the bounds of medical-legal confidentiality.

(d) Compilation and maintenance.--To ensure suitability of donated tissues for transplantation, records shall be made concurrently with the performance of each step of processing of tissue allografts. Distribution records shall be available but these may be collected and stored separately. All records shall be legible and indelible, shall identify the person or persons performing the procedures and shall include the dates of written entry. All records concerning allografts furnished to a particular surgeon shall be made available to that surgeon on request. The only exception is information infringing upon donor confidentiality. All records shall be maintained for a minimum of ten years.

(e) Inventory.--A record of all unprocessed, processed and distributed tissues shall be maintained.

(f) Confidentiality of patient records.--The following shall apply:

(1) The tissue bank shall have a procedure for ensuring the confidentiality of patient records. Information from or copies of records may be released only to authorized department employees, to the medical examiner or coroner in cases which are his, to other licensed agencies in Pennsylvania and other agencies elsewhere participating with the recovery, processing or distribution of tissue.

(2) Original medical records may be released by the tissue bank only in accordance with applicable Federal and State laws, court orders or subpoenas.

(3) The tissue bank shall have policies which ensure that unauthorized individuals cannot gain access to or alter patient records.

Section 712. Documentation of donor information.

The records shall include all information on the donor, including laboratory reports, autopsy reports if an autopsy is performed, a clinical history, a tissue procurement record and related material. The records of the permission to procure the tissue are kept permanently. A final summary statement is written by the medical director as to the medical assurance that the allografts which have been made available to the transplant surgeon meet the requirements of this statute, regulations promulgated hereunder and other applicable law and regulations.

Section 713. Facilities and equipment.

(a) Facilities generally.--Facilities of the tissue bank shall be designed for the specialized purposes for which they are to be used and shall be maintained in a clean and orderly manner. All instruments and equipment shall be subject to regularly scheduled maintenance and calibration. Refrigerators and freezers shall be inspected on a regularly scheduled basis

as described in the procedure manual and equipped with verifiable methods for proper temperature monitoring. Environmental monitoring procedures shall be established and periodic sampling of air, drains, surfaces and water faucets shall be documented.

(b) Operating room.--If the tissue bank has an operating room, it shall be reserved for the procurement or processing of cadaveric tissue. This may allow for the procurement of tissues on a 24-hour basis. The operating room shall have air filtration, stainless steel furniture and washable walls. Ultraviolet lights and bacterial filters may be utilized to reduce the ambient bacterial flora.

(c) Access.--Access to the tissue bank shall be limited to authorized persons, including department employees. An adequate security system or physical configuration shall be provided to prevent entry of unauthorized persons.

(d) Conformance with certain specifications.--Facilities in which tissues are processed for transplantation shall conform to specifications as may be delineated by the United States Food and Drug Administration.

Section 714. Procurement and processing procedures.

Tissues shall be removed using either sterile or clean, nonsterile techniques. If removed using sterile techniques, methods shall be consistent with standard operating room practice. Sterile technique does not necessarily preclude the need for subsequent tissue sterilization. Allografts procured using clean, nonsterile techniques are suitable for transplantation if adequate precautions are taken to identify and eliminate microorganisms. Tissues shall be processed into specimens appropriate for clinical use. The specific methods

employed may vary with each type of tissue and with the manner in which it has been procured, but each type of tissue shall be prepared according to written tissue bank procedures. Sterile bone and tissue allografts shall be processed and packaged in room class 100 environments, subject to United States Food and Drug Administration requirements. All processing of tissues shall conform to specifications as may be delineated by the United States Food and Drug Administration.

Section 715. Labeling.

(a) Visual inspection.--A sufficient area of the container shall remain unobstructed for its full length or circumference when the label has been affixed to the container to permit inspection of the contents.

(b) Container label.--Containers shall be labeled so as to meet any FDA requirements and identify the following:

(1) Name of the product.

(2) Name and address of the tissue bank.

(3) Tissue identification number.

(c) Package label.--Packages shall be labeled so as to identify the following:

(1) Name of tissue.

(2) Name and address of tissue bank.

(3) Tissue identification number.

(4) Expiration date, if applicable.

(5) Sterilization procedure used, if applicable.

(6) Preservative used and its concentration, or if no preservative is used or a combination of the foregoing as needed for an accurate description of the contents, whichever is applicable.

(7) Recommended storage temperature.

(8) Special instructions indicated by the particular product, for example, "Do Not Freeze."

Section 716. Packaging.

(a) General rule.--Packaging shall maintain sterility of the contents and maintain integrity of the appropriate container. Tissues which are vacuum sealed shall be spark-tested prior to distribution.

(b) Package insert.--All tissues shall be accompanied by a package insert which contains instructions for proper storage and reconstituting when appropriate. Specific instructions shall be enclosed with tissues requiring special handling. These instructions shall, subject to United States Food and Drug Administration requirements, include:

(1) Presence of known sensitizing substances or reference to an enclosed package insert containing appropriate information.

(2) Type and calculated amount of antibiotics added during processing.

(3) Source of the tissue, when it is a factor in safe administration.

(4) The results of all infectious disease tests performed.

(5) If tissue has been subjected to terminal sterilization, the method of terminal sterilization shall be clearly identified.

(6) Residual capable of harming a recipient.

Section 717. Tissue tracking.

(a) Tissue identification number.--Each tissue and any components derived therefrom shall be assigned, in addition to generic designation, one unique tissue identification number

which shall serve as a lot number to identify the material during all steps from procurement through distribution and utilization. Donor number and lot number should be the same.

(b) Hospital record system.--All Commonwealth hospitals which obtain or utilize tissue for transplantation shall employ a record system to document the movement of each tissue.

(c) Record system of other users.--All transplant surgeons and other users which obtain or utilize tissue for transplantation shall employ a record system to document the movement of each tissue.

Section 718. Fair and equitable system.

Tissue banks shall establish and document a system of distribution. Access to tissue shall be provided without regard to recipient sex, age, religion, race, creed, color or national origin. Documentation of distribution (date of requests for, offer of and delivery of tissue) shall be available for examination by authorized individuals, including department employees.

CHAPTER 9

EYE BANK STANDARDS

Section 901. Organizational requirements.

(a) Fiscal stability and documentation of service area.--Each eye bank shall:

(1) Have accounting and other fiscal procedures necessary to assure the fiscal stability of the organization.

(2) Make available to the department documentation of its service area.

(b) Board of directors or advisory board.--The eye bank shall have an advisory board which provides consultation and direction on all policymaking decisions as well as issues of

liability, fiduciary responsibility and selection of the agency director. Where the agency operates within the jurisdiction of an educational institution, the responsibilities of this board should not conflict with the responsibilities or span of control of the duly authorized administrator of the agency.

(c) Staff.--

(1) Each eye bank shall have an agency director who shall be the individual responsible for the daily operation of the eye bank. It is this individual's responsibility to:

(i) Carry out the policies of the eye bank's board of directors, advisory board or other governing body.

(ii) Determine what tissues are to be procured.

(iii) Prescribe clinically acceptable means for processing, quality control, storage and distribution.

(iv) Ensure that the eye bank performs only functions which the eye bank is equipped to perform, such as identification of eye donors.

(v) Act as a liaison between and among donors, physicians and recipients.

(vi) Procure and evaluate eye tissues.

(2) The agency director shall appoint technical staff and ensure that staff has the appropriate qualifications and training for the performance of their job responsibilities. The agency director shall ensure that there are a sufficient number of qualified eye bank technicians and supportive technical staff to promptly and proficiently perform all eye bank laboratory tests and procedures.

(3) The agency director, if not a physician, shall consult with the medical director, as well as other medical and legal authorities, in carrying out prescribed

responsibilities as necessary. The agency director shall provide all staff members with adequate information to perform their duties safely and competently.

(4) The agency director shall prescribe tests and procedures for measuring, assaying or monitoring properties of tissues essential to the evaluation of their safety for transplantation, for example, hepatitis B surface antigen and human immunodeficiency virus (HIV) antibody, and to conform with Federal and State laws and requirements. Results of all such tests or procedures, together with evaluations based on these findings, shall become part of the permanent record of all tissues processed.

(5) Each eye bank shall employ or have under contract a Commonwealth licensed physician medical director who provides indirect supervision to all coordinators, technicians and all other staff who assist in the medical management of donors or in the surgical procurement of cornea and eyes for transplantation or research. The medical director shall have demonstrated an expertise in external eye disease, corneal surgery or research or teaching in cornea or external disease. If the medical director has not served a corneal fellowship, the eye bank shall have and document a consulting relationship with an ophthalmologist who has.

(6) A supervisory eye bank technician shall be the individual responsible for the daily operation of the eye bank laboratory. The supervisory eye bank technician shall insure compliance with these standards for the eye bank laboratory. Each eye bank processing laboratory must have at least one certified technician in a supervisory role. An eye bank technician shall be trained in acquisition, evaluation

and distribution of eye tissue for transplantation, teaching and research. A procurement technician shall be proficient in screening, procuring and arranging transportation for eye tissue.

(d) Training certification and continuing education.--

(1) An eye bank shall provide an orientation program for each new technician, and the employee's participation shall be documented.

(2) An eye bank shall provide educational opportunities, such as inservice training programs, attendance at meetings, seminars and workshops for all technical personnel, including laboratory supervisors, at a frequency that is defined and reasonable for the size and needs of the technical staff.

(3) To be certified, an eye bank technician must pass the Eye Bank Association of America's (EBAA) technician certification examination or an approved examination administered by a department of ophthalmology-approved for residency training in ophthalmology.

(4) To be eligible for certification, the eye bank technician shall be employed by an eye bank and shall have at least one of the following:

(i) A high school diploma or GED, plus the EBAA Technician Training course or Department of Ophthalmology-approved training course, plus one year's work experience in eye banking.

(ii) Be a Certified Ophthalmic Technician (COT), licensed medical laboratory technician or licensed vocational/practical nurse, and have six month's eye bank work experience, and have completed either the EBAA Technician Training course or the Department of

Ophthalmology training course.

(iii) A Bachelor of Science or Bachelor of Arts degree, or higher, and either the EBAA Technician Training course or the Department of Ophthalmology training course.

(iv) Be a medical technologist, physician's assistant (PA), registered nurse (RN) or Certified Ophthalmic Technologist (COMT), and have three month's eye bank work experience.

Section 902. Community involvement and education.

The eye bank shall assist hospitals in establishing and implementing protocols for making routine inquiries about tissue donations by potential donors. The eye bank shall conduct and participate in education concerning tissue procurement for professionals and laypeople. The eye bank shall aid the department in the evaluation of the effectiveness of the agency in acquiring potentially available tissue.

Section 903. Quality assurance.

(a) General rule.--Each eye bank shall have an established quality assurance program. This program shall include ongoing monitoring and evaluation of activities, identification of problems and development of plans for corrective action. These standards shall provide the basis for development of the quality assurance program. Each eye bank shall document all aspects of its quality assurance program and maintain records of all quality assurance activities for a minimum of ten years.

(b) Reporting of adverse reactions.--The eye bank's quality assurance program shall include a method for the transplanting surgeon to report adverse reactions from the transplantation of corneal, scleral or other ocular tissue to the source eye bank

which in turn shall forward the adverse reaction information to the department under section 302.

Section 904. Performance standards.

(a) Performance measures.--Each eye bank shall demonstrate proficiency in all aspects of eye banking by annually procuring, processing and distributing at least 50 corneas for penetrating keratoplasty and provide the department with documentation of its performance.

(b) Policy required.--Each eye bank shall have a consistent policy for the physical inspection of the donor and examination and documentation of the prospective donor's available medical record or death investigation.

(c) Review of records.--Review of all available records on each donor shall be performed by an individual who is qualified by profession, education or training to do so and who is familiar with the intended use of the tissue.

Section 905. Donor selection.

(a) Keratoplasty.--Tissue from donors with any of the following conditions are potentially health threatening for the recipient or pose a risk to the success of the surgery and shall not be offered in the United States for penetrating keratoplasty:

(1) Death of unknown cause.

(2) Death from central nervous system diseases of unknown etiology.

(3) Creutzfeldt-Jacob disease.

(4) Subacute sclerosing panencephalitis.

(5) Progressive multifocal leukoencephalopathy.

(6) Congenital rubella.

(7) Reyes syndrome.

(8) Active viral encephalitis of unknown origin.

(9) Active septicemia (bacteremia, fungemia or viremia).

(10) Active bacterial or fungal endocarditis.

(11) Active viral hepatitis.

(12) Rabies.

(13) Intrinsic eye disease:

(i) retinoblastoma;

(ii) malignant tumors of the anterior ocular segment;

(iii) active ocular or intraocular inflammation (conjunctivitis, scleritis, iritis, uveitis, vitreitis, choroiditis or retinitis);

(iv) congenital or acquired disorders of the eye which would preclude a successful outcome for the intended use, for instance, a central donor corneal scar for an intended penetrating keratoplasty, keratoconus and keratoglobus; or

(v) pterygia or other superficial disorders of the conjunctiva or corneal surface involving the central optical area of the corneal button.

(14) Prior intraocular or anterior segment surgery:

(i) refractive corneal procedures, for instance, radial keratotomy or lamellar inserts;

(ii) laser photoablation surgery;

(iii) anterior segment surgery, for instance, cataract intraocular lens implant glaucoma filtration;

(iv) laser surgical procedures such as argon laser trabeculoplasty, retinal and panretinal photocoagulation do not necessarily preclude use for penetrating keratoplasty, but should be cleared by the medical

director.

(15) Active leukemia.

(16) Active disseminated lymphomas.

(17) Hepatitis B surface antigen positive donors.

(18) Recipients of human pituitary-derived growth hormone (pit-hGH) during the years 1963 through 1985.

(19) Human immunodeficiency virus (HIV) seropositive donors.

(20) Acquired immunodeficiency syndrome (AIDS).

(21) Children under 13 years of age and infants of mothers with AIDS or at high risk of HIV infection.

(22) High risk for HIV infection based on data on AIDS cases published by the United States Public Health Service, Centers for Disease Control and as described under section 313.

(23) HTLV-I or HTLV-II infection.

(24) Active syphilis.

(25) Hepatitis C seropositive donors.

(b) Lamellar or patch grafts.--Tissue from donors meeting the criteria under subsection (a) shall not be used for lamellar or patch grafts with the exception that tissue with local eye disease affecting the corneal endothelium or previous ocular surgery that does not compromise the corneal stroma, for instance, aphakia or iritis, is acceptable for use.

(c) Epikeratoplasty.--Tissue from donors meeting the criteria under subsection (a) shall not be used for epikeratoplasty, with the exception that tissue with local eye disease affecting the corneal endothelium, for instance, aphakia or iritis, is acceptable for use. Interval of time from donor's death to preservation of eye tissue may be extended.

(d) Surgery.--Tissue from donors meeting the criteria under subsection (a) shall not be used for surgery with the exception that tissue with local eye disease affecting the corneal endothelium, for instance, aphakia or iritis, is acceptable for use. The interval of time from the donor's death to preservation of the scleral/eye tissue may be extended.

(e) Donor age.--To date, no definite relationship has been established between the quality of donor tissue and the age of the donor. Therefore, the upper and lower age limit of donors is left to the discretion of the medical director.

Section 906. Method of consent.

Documentation of legal consent for enucleation or in situ procurement is essential for medical-legal reasons. Consent procedures and forms must conform with 20 Pa.C.S. Ch. 86 (relating to anatomical gifts), and documentation for consent shall be retained.

Section 907. Testing.

(a) Standard.--Verification of satisfactory compliance with the College of American Pathologists' (CAP) proficiency testing program shall be documented and made available to authorized individuals, including department employees.

(b) Microbiologic culturing.--Culturing of eye bank donor eyes is advised despite the recognition that positive bacteriologic results do not necessarily lead to infection. Presurgical cultures, at-time-of-surgery cultures or postoperative cultures may not correlate and they may not correlate with a postoperative infection. However, the responsibility for determining the need for culturing shall reside with the transplanting surgeon. The following shall apply:

(1) Eye banks may elect to perform corneal-scleral rim cultures at the time of corneal preservation in tissue culture medium. Positive culture reports shall be reported to the receiving surgeon or recipient eye bank.

(2) Each eye bank shall recommend culturing of the corneal-scleral rim for corneal transplantation or a piece of sclera for scleral implantation at the time of surgery. Positive culture results in cases of postoperative infection shall be reported to the eye bank that processed the tissue.

(c) Human immunodeficiency virus (HIV) screening.--

(1) Each eye bank shall have an HIV screening program using United States Food and Drug Administration (FDA) approved tests for all donors of surgically designated tissue. A negative screening test shall be documented prior to release of tissue for transplantation.

(2) When a donor has had a blood transfusion within the 48 hours preceding cessation of circulatory function, that is, a nonheartbeating donor, a pretransfusion sample shall be obtained to test for HIV. If a pretransfusion sample is unavailable and if the adult donor has received four or more units of whole blood or an equivalent within the 48 hours preceding cessation of circulatory function or if a child under 12 years of age has received any transfusion of blood or nonsterilizable fraction, the donor tissue is unacceptable for transplantation and shall be considered potentially hazardous and labeled as such.

(d) Hepatitis B screening.--Each eye bank shall have a hepatitis B screening program using an FDA-approved test for hepatitis B surface antigen for all donors of surgically designated tissue. A negative screening test or neutralization

or confirmatory test must be documented prior to release of tissue for transplantation.

(e) Hepatitis C screening.--Each eye bank shall have a hepatitis C screening program using an FDA-approved test for hepatitis C surface antigen for all donors of surgically designated tissue. A negative screening test or neutralization or confirmatory test must be documented prior to release of tissue for transplantation.

(f) HTLV-I and HTLV-II screening.--Donor screening for HTLV-I and HTLV-II is not required. However, it is recommended that each eye bank have an HTLV-I and HTLV-II screening program. If donor screening for HTLV-I and HTLV-II has been performed, a negative screening test shall be obtained and documented prior to release of tissue for transplantation.

(g) Syphilis screening.--Donor screening for syphilis is not required. However, it is recommended that each eye bank have a syphilis screening program. If the screening test is performed and it is positive, a negative confirmatory test shall be obtained and documented prior to release of tissue for transplantation.

Section 908. Documentation of donor information.

(a) Donor record.--Donor screening forms or copies of medical charts, medical examiner or coroner review forms and gross autopsy results shall be completed and retained on all donated eye tissue as part of the donor record.

(b) Donor information forms.--Donor information forms shall contain information regarding the circumstances surrounding the death of the donor and medical history so that the suitability of the tissue for transplantation may be evaluated.

(c) Minimum information to be retained.--A report form for

retaining donor and recipient information shall be established for permanent record and shall be readily accessible for inspection by authorized individuals, including department employees. The record shall include the following minimum information:

(1) The eye bank identification number that is unique to each tissue graft.

(2) The name of the eye bank.

(3) The location of the eye bank.

(4) The telephone number of the eye bank.

(5) The type of preservation.

(6) The age of the donor.

(7) The cause of death.

(8) The death date and time.

(9) The enucleation or in situ procurement date and time.

(10) The preservation date and time.

(11) The slitlamp report.

(12) Specific microscopy, if performed.

(13) The name of the enucleator/evaluator/technician.

(14) The name of the surgeon receiving the tissue.

(15) Recipient identification.

(16) Utilization of nontransplantable tissue.

(17) All serological or microbiological tests performed.

(18) Adverse reactions, when reported.

(d) Length of storage.--All records shall be maintained for a minimum of ten years from the date of transplantation or implantation.

Section 909. Facilities and equipment.

(a) Facilities generally.--Each eye bank shall have

sufficient space, equipment and supplies to perform the volume of laboratory services with optimal accuracy, efficiency, sterility, timeliness and safety.

(b) Laboratory.--The laboratory shall be a separate area with limited access in which activities directly related to eye banking are carried out. The laboratory shall have a sink with a drain and running water. There shall be adequate counter space for preparation of donor material. The room, including walls, floor and sink, shall be kept clean at all times. Appropriate documentation of regular laboratory cleaning schedules shall be maintained.

(c) Equipment.--Each eye bank laboratory shall have an adequate stable electrical source and a sufficient number of grounded electrical outlets for operating laboratory equipment. Laminar flow hoods or a similar piece of equipment shall be available for sterile processing.

(d) Refrigeration.--Each eye bank laboratory shall have a refrigerator with a device for recording temperature variations. Temperature variations shall be recorded daily and remain within the range of two degrees to six degrees Celsius. These records shall be kept for a minimum of seven years. The refrigerator shall be maintained for the exclusive use of donor-related material and shall contain clearly defined and labeled areas for all tissue stored, that is, quarantined tissue, surgical tissue awaiting distribution and research tissue.

(e) Power failures.--In the event of a power failure, there shall be a procedure for immediate notification and action to be taken and includes an emergency power supply to maintain essential refrigeration.

(f) Maintenance records.--Appropriate maintenance and

certification records shall be maintained on each piece of equipment. These records shall show dates of inspection, performance evaluations and any maintenance procedures or repairs performed.

(g) Cleaning procedures.--The eye bank shall include in its procedures manual the monitoring, inspection and cleaning procedures and schedules for each piece of equipment. Documented cleaning schedules for laboratory equipment shall be maintained.

(h) Expiration dates.--All sterilized instruments, supplies and reagents, such as corneal preservation medium, shall contain expiration dates that are current at all times.

(i) Length of storage.--All maintenance records shall be kept for ten years.

Section 910. Satellite laboratories.

Satellite laboratories that procure, process and distribute tissue shall have a certified technician and be supervised by and have access to a qualified medical director or designee. Satellite laboratories shall be inspected by department employees as part of the licensing process for the parent eye bank.

Section 911. Procurement and processing procedures.

(a) Enucleation procedure.--Ultimate responsibility for personnel to perform enucleation rests with the agency director and the medical director.

(b) In situ and laboratory removal of the corneoscleral rim.--Removal of the corneoscleral rim shall be performed using sterile technique by individuals specifically trained in situ procurement or laboratory removal of the corneoscleral segment.

(c) Use of preservation medium.--Eye banks shall use an appropriate corneal storage medium which has been manufactured

in accordance with United States Food and Drug Administration good manufacturing practices. The medium shall be used and stored according to the manufacturer's recommendations for temperature, date and other factors.

(d) Long-term preservation.--Eye banks employing long-term preservation of corneal tissue, such as organ culturing, shall carefully document the procedure in their procedures manual and adhere to strict aseptic technique.

(e) Whole globe preservation.--Eye banks that store whole eyes for lamellar or refractive keratoplasty shall employ aseptic practices using one of the preservation methods given in the eye bank's procedures manual. The selected preservation method shall be documented in the eye bank's own procedure manual.

(f) Scleral preservation.--

(1) Eye banks shall preserve scleral tissue. The selected preservation method shall be documented in the eye bank's own procedure manual.

(2) An expiration date for use of tissue shall be indicated based on the container capability or factors documented or recommended by the eye bank.

(g) Interval between death, enucleation, procurement and preservation.--Acceptable time intervals from death, enucleation or procurement to preservation of eye tissue may vary according to the circumstances of death and interim means of storage of the body. It is generally recommended that corneal preservation occur as soon as possible after death. All time intervals, that is, time of death to the time of enucleation and preservation or the time to corneal procurement, shall be recorded for each donor.

(h) Eye maintenance prior to enucleation.--The prospective donor's corneal integrity shall be maintained. Procedures for eye maintenance shall be described in the eye bank's procedures manual. Each individual eye bank's procedure is left to the discretion of the medical director and shall be clearly documented and adhered to.

(i) Review of donor medical history.--Prior to distribution of tissue for transplantation, the medical director or designee shall review and document the medical and laboratory information in accordance with medical standards.

(j) Nonsurgical donor tissue.--If donor tissue provided for purposes other than surgery, for instance, research or practice surgery, and if that donor tissue is not screened for human immunodeficiency virus (HIV), hepatitis or syphilis, a label stating that screening for HIV-antibody, hepatitis B, hepatitis C or syphilis has not been carried out or stating "Potentially Hazardous Biological Material" shall be attached to the container used for the donor tissue storage or transport.

Section 912. Tissue evaluation.

(a) General rule.--The transplanting surgeon has ultimate responsibility for determining the suitability of the tissue for transplantation.

(b) Gross examination.--The corneal-scleral segment shall be initially examined grossly for clarity, epithelial defects, foreign objects, contamination and scleral color, for example, jaundice.

(c) Slitlamp examination.--The cornea shall be examined for epithelial and stromal pathology and in particular endothelial disease. Enucleated whole globes shall be examined in the laboratory prior to distribution or corneal procurement. After

corneal procurement, the corneal-scleral rim shall be evaluated by slitlamp biomicroscopy, even if the donor eye has been examined with the slitlamp prior to procurement of the corneal-scleral rim, to insure that damage to the corneal endothelium or surgical detachment of Descemet's membrane did not occur.

(d) Specular microscopy.--Specular microscopy may provide useful information in screening donor corneal tissue to determine suitability for transplantation.

Section 913. Storage.

All surgical tissue shall be stored in quarantine until results of human immunodeficiency virus (HIV), HBsAg and HCV and any other relevant donor screening tests have been recorded as nonreactive. All tissue shall be stored at a temperature appropriate to the method of preservation used. Each eye bank shall precisely document its procedures for storage.

Section 914. Documentation of recipient information.

Each eye bank shall retain recipient information on each surgically used tissue as provided by the transplanting surgeon for a period of ten years.

Section 915. Confidentiality.

The eye bank shall have a procedure for ensuring the confidentiality of patient records. Information from or copies of records may be released only to appropriate staff, the medical examiner or coroner and to authorized department employees. The eye bank must ensure that unauthorized individuals cannot gain access to or alter patient records. Original medical records may be released by the eye bank only in accordance with applicable Federal or State laws, court orders or subpoenas.

Section 916. Labeling.

(a) Visual inspection.--A sufficient area of the container shall remain unobstructed for its full length or circumference when the label has been affixed to the container to permit inspection of the contents.

(b) Label contents.--Each corneal or scleral tissue shall be clearly and indelibly labeled to include, at least, the following:

(1) The name of the source eye bank.

(2) The tissue identification number.

(3) The type of tissue.

(4) The date and time of the donor's death.

(5) The date and time of the corneal/scleral preservation.

(6) The expiration date for the scleral tissue.

(7) A statement accompanying the tissue, stating that:

(i) the tissue is intended for single patient application only and that it is not to be considered sterile and that the United States Food and Drug Administration (FDA) therefore recommends culturing or reculturing; and

(ii) the tissue was procured form a donor who was nonreactive when tested for human immunodeficiency virus (HIV) antibody, hepatitis B surface antigen (HBsAg) and hepatitis C antibody (HCV), using a test approved by the FDA.

Section 917. Packaging.

(a) Procedure.--Each tissue shall be individually packaged and sealed with a shrink wrap. The tissue shall be packed in a waterproof container with wet ice, so as to maintain the temperature of the tissue at an acceptable level. Packing shall

be done so that the package insert and tissue label do not become wet. Special instructions shall be included on the package insert.

(b) Package insert.--A package insert form shall accompany the tissue for transplantation. This form shall include the following:

(1) Recommended storage temperature with specific emphasis on "DO NOT FREEZE."

(2) A recommendation that the surgeon should check for integrity of the seal and immediately report to the eye bank any evidence of possible tampering.

(3) Notice that color change per the manufacturer's guidelines may indicate a change in pH, in which case the tissue should not be used and a report made immediately to the eye bank.

(4) Information as to whether presurgical microbiologic cultures were performed by the eye bank, including the advisement that culture of the donor rim and sclera should be performed at the time of surgery.

(5) An advisory to the receiving surgeon that the tissues are delivered with no warranty as to merchantability or fitness for a particular purpose and that the receiving surgeon is ultimately responsible for judging if the tissue is suitable for use.

Section 918. Verification of death.

Where applicable, the eye bank shall assure that death has been determined in accordance with the act of December 17, 1982 (P.L.1401, No.323), known as the Uniform Determination of Death Act, and documented in the donor's medical record.

Section 919. Fair and equitable system.

Eye banks shall establish and document a system of distribution. Access to tissue shall be provided without regard to recipient sex, age, religion, race, creed, color or national origin. Documentation of distribution (date of requests for, offer of and delivery of eye tissue) shall be available for examination by authorized individuals, including department employees.

CHAPTER 11

INSPECTIONS AND PLAN OF CORRECTIVE ACTION

Section 1101. Inspections and investigations.

The department shall make or cause to be made unannounced inspections and investigations:

(1) To assure compliance with the standards.

(2) To evaluate the accrediting process of professional organizations.

(3) To respond to written complaints submitted to the department.

Section 1102. Inspections and plans of correction.

The department shall conduct a licensure inspection of all agencies every two years to assure compliance with the general standards in Chapters 3, 5, 7 and 9, as appropriate. All deficiencies to the standards will be submitted in writing to the agency by the department. Within ten working days of written notification by the department, the agency shall submit to the department for approval a written plan of correction, including a time table when corrections will be made. At the termination of an approved plan of correction, the department shall conduct a second inspection to determine agency compliance with the standards. If an agency fails to correct the deficiencies noted in the plan of correction, the department shall take action

under Chapter 17.

Section 1103. Departmental action and plan of correction.

If, as the result of an inspection in response to a complaint, the department determines that an agency is out of compliance with this act, the department shall take action under Chapter 17. In addition, the agency shall submit a plan of correction to the department for approval. If the agency remains out of compliance with the requirements of this act upon completion of the plan of correction and subsequent inspection by the department, further action as defined under Chapter 17 may be taken.

CHAPTER 13

REPORTING REQUIREMENTS

Section 1301. Financial statement.

Each agency licensed by the department shall submit to the department an annual audited financial statement, signed by the agency director or the agency's board president. The annual audited financial statement shall be submitted to the department no later than six months after the end of the agency's most recently completed fiscal or operational year and within 30 days of receipt by the agency.

Section 1302. Organ and tissue procurement, distribution and revenues.

Each agency shall submit to the department the data described under section 319. Data shall be submitted annually. Data shall be submitted to the department within 30 days of the agency's receipt of its annual audited financial statement as described under section 1301.

CHAPTER 15

ADVERSE REACTIONS

Section 1501. Adverse reactions generally.

Each agency shall inform physicians and hospital personnel involved in the transplantation of organs, tissues and eyes of policies and procedures regarding the reporting of adverse reactions to agencies.

Section 1502. Notification of adverse reaction.

In accordance with section 315, each agency shall, upon notification of an adverse reaction by a transplanting physician or hospital:

(1) Immediately notify the department of a report of adverse reaction.

(2) Immediately suspend distribution of grafts coming from that donor.

(3) Initiate an investigation to determine whether or not the adverse reaction was due to the donor organ or tissue.

(4) Submit a report of adverse reaction required under section 315.

Section 1503. Follow-up procedures.

Where it is determined that the adverse reaction was due to the donor organ or tissue, each agency shall institute recall procedures in accordance with section 316 and look-back procedures in accordance with section 317.

CHAPTER 17

DENIAL, REVOCATION OR SUSPENSION OF LICENSE AND FINES

Section 1701. General standards.

The department may deny, revoke or suspend a license or impose a fine of not more than $500 per day per violation for any of the following actions:

(1) Making false statements on an application or on any document associated with licensure.

(2) Advertising false services or credentials.

(3) Failing to pay within 30 days of assessment trust fund assessments in accordance with section 1904.

(4) Failing to correct deficiencies within the time required by the department.

(5) Failing to submit an annual income statement and annual data on organ and tissue procurement, distribution and revenues specified under section 319.

(6) Failing to inform the department of an adverse reaction or failing to comply with all provisions of Chapter 15.

(7) Operating an agency which retrieves tissues or eyes in this Commonwealth but does not distribute tissues or eyes to the citizens of this Commonwealth.

(8) Violating or aiding and abetting in the violation of any other provision of this act.

(9) Violating an agency moratorium as described under section 1708.

Section 1702. Denial of license.

In addition to the reasons under section 1701, the department may deny a license to an applicant who owns or operates an agency which, during the 12 months prior to the application for a license, has had a license revoked under section 1701, had a moratorium imposed on agency activities, had injunction proceedings initiated against it or had a receiver appointed.

Section 1703. Determination of action to be taken.

In determining if a sanction, including a fine, is to be imposed and in determining the terms of the action, the

department shall consider the following factors:

(1) The gravity of the violation, including the probability that death or serious physical harm will result or has resulted, the severity of the potential harm and the extent to which the provisions of the applicable law or regulations were violated.

(2) Actions taken by the owner or administrator to correct violations.

(3) Any previous violations.

(4) The financial benefit to the facility of committing or continuing the violation.

Section 1704. Notice to agency.

When department action is taken against an agency, the department shall immediately serve the agency with written notice of the action by personal service or registered or certified mail, return receipt requested. This notice shall state the following:

(1) The reasons for the action.

(2) The terms of the action, including the daily amount of any fine.

(3) The period of the action.

Section 1705. Review of department action.

Each agency receiving a written notice of department action has the right to appeal. Procedures for appeal and hearing shall be in accordance with 2 Pa.C.S. (relating to administrative law and procedure).

Section 1706. Actions taken subsequent to hearing.

If, as a result of a hearing, an action taken by the department is upheld, the action shall be immediately imposed and, in the case of a fine, the violator shall pay the fine plus

interest for each day beyond the date set by the department for payment of the fine.

Section 1707. Reapplication procedures.

Following denial or revocation of a license, an agency shall be permitted to reapply for a license in accordance with the provisions of section 301.

Section 1708. Moratorium on agency activities.

The department may impose a moratorium on all or selected agency activities which the department determines to be a potential threat to the health, safety or welfare of the public.

CHAPTER 19

ORGAN AND TISSUE PROCUREMENT AND TRANSPLANTATION ADVISORY BOARD

Section 1901. Organ and Tissue Procurement and Transplantation Advisory Board.

There is hereby established the Organ and Tissue Procurement and Transplantation Advisory Board which shall consist of 14 members who are appointed by and shall report directly to the Secretary of Health. The membership must be regionally distributed and shall include the following:

(1) Two representatives who have expertise in vascular organ transplant surgery.

(2) Two representatives who have expertise in vascular organ procurement, preservation or distribution.

(3) Two representatives who have expertise in musculoskeletal tissue transplant surgery.

(4) Two representatives who have expertise in musculoskeletal tissue procurement, processing or distribution.

(5) One representative who has expertise in eye and

cornea transplant surgery.

(6) One representative who has expertise in eye and cornea procurement, processing or distribution.

(7) One representative who has expertise in bone marrow procurement, processing or transplantation.

(8) One representative from the Pennsylvania Pediatric Society.

(9) One representative from the Pennsylvania Society of Pathologists who has expertise with regard to infectious diseases.

(10) One representative who is a medical examiner or coroner.

Section 1902. Compensation and terms of office of board members.

The advisory board members may not be compensated for their services, except that they may be reimbursed for their travel expenses. Members of the board shall be appointed for three-year terms of office, except that, initially, five members shall be appointed for one-year terms, four members shall be appointed for two-year terms and four members shall be appointed for three-year terms.

Section 1903. Advisory board duties.

The advisory board in consultation with the agencies shall:

(1) Assist the department in the development of necessary professional qualifications, including, but not limited to, the education, training and performance of persons engaged in the various facets of organ and tissue procurement, processing, preservation and distribution for transplantation.

(2) Assist the department in monitoring the appropriate

and legitimate expenses associated with organ and tissue procurement, processing and distribution for transplantation and developing methodologies to assure the uniform Statewide reporting of data to facilitate the accurate and timely evaluation of the organ and tissue procurement and transplantation system.

(3) Develop with and recommend to the department the necessary procedures and protocols required to assure that all residents of this Commonwealth have fair access to available organ and tissue transplantation therapy and that residents of this Commonwealth can be reasonably assured that the Statewide procurement transplantation system will be able to fulfill their organ and tissue requirements within the limits of the available supply and according to the severity of their medical condition and need.

(4) Develop with and recommend to the department any changes to the laws of this Commonwealth or administrative rules or procedures required to assure that the Statewide organ and tissue procurement and transplantation system will be able to function smoothly, effectively and efficiently and in a manner which assures the residents of this Commonwealth that no person or entity profits from the altruistic voluntary donation of organs or tissues.

Section 1904. Organ and Tissue Procurement Trust Fund.

(a) Assessment of fees.--The department shall assess annual fees to be used for the licensure program and the advisory board in the following amounts, which shall not exceed $35,000 per organization:

(1) Each general organ procurement organization shall pay the greater of $1,000 or 0.5% of its total revenues

produced from procurement, processing or distributing activity in this Commonwealth by the licensee during its most recently completed fiscal year or operational year.

(2) Each tissue bank shall pay the greater of $1,000 or 0.5% of its total revenues from procurement, processing or distributing activity in this Commonwealth by the licensee during its most recently completed fiscal year or operational year.

(3) Each eye bank shall pay the greater of $500 or 0.5% of its total revenues produced from procurement, processing or distributing activity in this Commonwealth by the licensee during its most recently completed fiscal year or operational year.

(b) Organ and Tissue Procurement Trust Fund.--There is created the Organ and Tissue Procurement Trust Fund in the State Treasury, into which the proceeds from fees must be deposited. Moneys in the trust fund must be used exclusively for the implementation, administration and operation of the licensure program and the advisory board.

(c) Applicability.--This section applies to organs, tissues or eyes which are initially procured within this Commonwealth or in another state and brought into this Commonwealth for processing, distribution or transplantation.

Section 1905. Assessment deadlines.

The department shall issue annual assessments to each agency on or before June 30 of each year. Each agency must pay its annual assessment by the close of business on July 31 of each year.

CHAPTER 21

MISCELLANEOUS PROVISIONS

Section 2101. Procurement of cadaveric organs for transplant by out-of-State physicians.

Any physician currently licensed to practice medicine and surgery in the United States may surgically procure in this Commonwealth cadaveric organs for transplant if:

(1) the organs are being procured for an out-of-State patient who is listed on the Organ Procurement Transplant Network as having next priority; and

(2) the organs are being procured through the auspices of an organ procurement organization licensed by this Commonwealth.

Section 2102. Effective date.

This act shall take effect in 60 days.