Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

ST - B0000 - Initial Comments

Title Initial Comments

Type Memo Tag

Regulation Definition

Interpretive Guideline

These guidelines are meant solely to provide guidance to surveyors in the survey process.

ST - B0001 - Definitions

Title Definitions

Type Rule

765.511 FS; 59A-1.003 FAC 765.523(1) FS

Regulation Definition

Interpretive Guideline

765.511 Definitions.-As used in this part, the term:
(1) "Agency" means the Agency for Health Care Administration.
(2) "Anatomical gift" or "gift" means a donation of all or part of a human body to take effect after the donor's death and to be used for transplantation, therapy, research, or education.
(3) "Bank" or "storage facility" means a facility licensed, accredited, or approved under the laws of any state for storage of human bodies or body parts.
(4) "Death" means the absence of life as determined, in accordance with currently accepted medical standards, by the irreversible cessation of all respiration and circulatory function, or as determined, in accordance with s. 382.009, by the irreversible cessation of the functions of the entire brain, including the brain stem.
(5) "Decedent" means a deceased individual whose body or

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

body parts may be, or are, the source of an anatomical gift.
(6) "Department" means the Department of Highway Safety and Motor Vehicles.
(7) "Disinterested witness" means a witness other than a person listed in s. 765.512(3) or other family member.
(8) "Document of gift" means any of the documents or mechanisms used in making an anatomical gift under s. 765.514.
(9) "Donor" means an individual who makes an anatomical gift of all or part of his or her body.
(10) "Donor registry" means a database that contains records of anatomical gifts and amendments to, or revocations of, such gifts.
(11) "Eye bank" means an entity that is accredited by the Eye Bank Association of America or otherwise regulated under federal or state law to engage in the retrieval, screening, testing, processing, storage, or distribution of human eye tissue.
(12) "Guardian" means a person appointed pursuant to chapter 744. The term does not include a guardian ad litem.
(13) "Hospital" means a hospital licensed, accredited, or approved under the laws of any state and includes a hospital operated by the United States Government or a state, or a subdivision thereof, although not required to be licensed under state laws.
(14) "Identification card" means an official identification card issued by a governmental entity, state agency, or subdivision thereof.
(15) "Organ procurement organization" means an entity that is designated as an organ procurement organization by the Secretary of the United States Department of Health and Human Services and that engages in the retrieval, screening, testing, processing, storage, or distribution of human organs.
(16) "Part of the body" or "body part" means an organ, eye, or tissue of a human being. The term does not include the whole

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

body.
(17) "Physician" or "surgeon" means a physician or surgeon licensed to practice under chapter 458 or chapter 459 or similar laws of any state. "Surgeon" includes dental or oral surgeon.
(18) "Procurement" means any retrieval, recovery, processing, storage, or distribution of human organs or tissues for transplantation, therapy, research, or education.
(19) "Procurement organization" means an organ procurement organization, eye bank, or tissue bank.
(20) "Reasonably available" means able to be contacted by a procurement organization in a timely manner without undue effort, and willing and able to act in a manner consistent with existing medical protocols necessary for the making of an anatomical gift.
(21) "Record" means information that is inscribed on a tangible medium or that is stored in an electronic or other medium and is retrievable in perceivable form.
(22) "Sign" or "signed" means, with the present intent to authenticate or adopt a record, to execute or adopt a tangible symbol, or attach to or logically associate an electronic symbol, sound, or process with the record.
(23) "Tissue bank" means an entity that is accredited by the American Association of Tissue Banks or otherwise regulated under federal or state law to engage in the retrieval, screening, testing, processing, storage, or distribution of human tissue.

59A-1.003 Definitions.
For the purpose of this section the word, phrase, or term:
(1) "Adverse reaction" means the patient's unfavorable physical response to the transplantation of an organ or tissue with regard to the transmission of infections of other diseases of potential danger.
(2) "Allograft" means the transplantation of tissue or organ taken from one individual of the same species as the recipient

but with different hereditary factors.
(3) "Brain death" means the determination of death in accordance with Section 382.009, F.S., where there is the irreversible cessation of the functioning of the entire brain, including the brain stem.
(4) "Certificate" means a license to operate as an organ procurement organization, tissue bank, or eye bank which is issued by the Agency for Health Care Administration.
(5) "Clean, non-sterile" means the use of methods and techniques that reduce gross contamination.
(6) "Consent" means authorization or permission to procure organ(s) or tissue(s) from a non-living donor 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 such donation and that minimize the possibility of coercion or undue influence.
(7) "Container (final container)" means the immediate unit, bottle, vial, ampule, tube, or other receptacle containing grafts as distributed.
(8) "Coordinators" means registered nurses, physicians' assistants, or other medically trained personnel who assist in the medical management of organ donors or in the surgical retrieval of organs.
(9) "Designee" means 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.
(10) "Distribution" means the shipment and delivery of final container grafts for recipient use.
(11) "Donation" means the free and voluntary gift of one or more organs or tissues for the purpose of transplant surgery.
(12) "Donor" means a medically acceptable person where appropriate permissions have been obtained to procure organ(s) and tissue(s) according to the provisions of Chapter 765, F.S., or if applicable, Chapter 406, F.S.

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

(13) "Facilities" means any area used for retrieval, processing, testing, storage, or distribution of organs, tissues, and tissue components.
(14) "Graft" means a piece of skin, bone, or other tissue to be transplanted to another place on the human body.
(15) "Gross autopsy" means the anatomical examination of a body without microscopic examination.
(16) "Indirect supervision" means the direction that is provided to coordinators and other staff under protocols expressly approved by the licensed physician medical director. The medical director or his physician designee shall always be available, in person or by telephone, to provide medical direction and consultation.
(17) "Label" means written, printed, or graphic matter on the container or package or any such matter clearly visible through the immediate carton, receptacle, or wrapper.
(18) "Next of kin" means the person or persons most closely related to a deceased individual as designated by Section 765.512, F.S.
(19) "Organ" means a body part such as a heart, kidneys, pancreas, liver, lungs, that requires vascular reanastomosis.
(20) "Organ Procurement and Transplantation Network (OPTN)" means the corporation under the Public Health Service Act that approves transplant programs to ensure that all organ donors meet minimum standards and requirements.
(21) "Package" means the immediate carton, receptacle, or wrapper, including all labeling matter therein and thereon, and the contents of the one or more enclosed containers.
(22) "Preservation" means the proper combination of conditions that serve to protect organs from decay during established periods.
(23) "Procedure" means a series of activities followed in a regular and definite order.
(24) "Processing" means the procedure employed after organ or tissue retrieval and before storage of the final container

material; includes identification of the organ or tissue, organ or tissue treatment, preparation of components from such organ or tissue, testing, labeling, and associated record-keeping.
(25) "Procure" means the removal of transplantable organs or tissues for the benefit of one or more patients.
(26) "Procurement" as it applies to an OPO and eye bank means the retrieval, processing or distribution of organs and eye tissues; procurement as it applies to a tissue bank means the retrieval, processing, storage or distribution of tissues.
(27) "Quality assurance" means the monitoring procedures that ensure and document that the entire agency (e.g., facilities, personnel, methods, practices, and records) conforms with these standards.
(28) "Quality control" means laboratory tests and procedures for measuring or monitoring properties of organs and tissues essential to the evaluation of their safety or usefulness.
(29) "Retrieval" means the excision of organs or tissues from a donor's body.
(30) "Storage" means the proper combination of conditions that serve to protect tissues from decay during established periods.
(31) "Tissue" means any non-visceral collection of human cells and their associated intercellular substances.
(32) "Tissue bank" means a public or private entity which is involved in at least one of the following activities: a) retrieving, processing, storing, or distributing viable or nonviable human tissues to clinicians who are not involved in the procurement process; b) retrieving, processing, and storing human tissues in one institution and making these tissues available to clinicians in other institutions; or c) retrieving, processing, and storing human tissues for individual depositors and releasing these tissues to clinicians at the depositor's request. Establishments such as transplantation centers and other hospitals which store tissue only for a short

term pending scheduled surgery within the same facility but do not otherwise participate in the retrieving, processing, or distribution of tissue would not be regulated under these provisions.
(33) "Transplant safety" means 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.
(34) "Transplant physician" means a licensed practitioner who performs surgical repair or replacement using organs or tissues donated by a living or non-living donor.

765.523 Discrimination in access to anatomical gifts and organ transplants prohibited.-
(1) As used in this section, the term:
(a) "Auxiliary aids and services" means:
1. Qualified interpreters or other effective methods of making aurally delivered materials available to individuals with hearing impairments.
2. Qualified readers, recorded texts, texts in an accessible electronic format, or other effective methods of making visually delivered materials available to individuals with visual impairments.
3. Supported decisionmaking services, including any of the following:
a. The use of a support person to assist an individual in making medical decisions, communicating information to the individual, or ascertaining his or her wishes.
b. The provision of information to a person designated by the individual, consistent with federal and state laws governing the disclosure of health information.
c. Measures used to ensure that the individual ' s guardian or legal representative, if any, is included in decisions involving the individual ' s health care and that medical decisions are in

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

accordance with the individual ' s own expressed interests.
d. Any other aid or service that is used to provide information in a format that is readily understandable and accessible to individuals with cognitive, neurological, developmental, or intellectual disabilities.
(b) "Covered entity" means any of the following:
1. A licensed health care practitioner as defined in s. 456.001.
2. A health care facility as defined in s. 408.07.
3. Any other entity responsible for potential recipients of anatomical gifts or organ transplants.
(c) "Disability" has the same meaning as "developmental disability" and "intellectual disability" as those terms are defined in s. 393.063.
(d) "Organ transplant" means the transplantation or transfusion of a part of a human body into the body of another individual for the purpose of treating or curing a medical condition.
(e) "Qualified individual" means an individual who has a disability and meets the clinical eligibility requirements for the receipt of an anatomical gift or an organ transplant, regardless of:
1. The support networks available to the individual;
2. The provision of auxiliary aids and services; or
3. Reasonable modifications to the policies, practices, or procedures of a covered entity pursuant to subsection (4).

ST - B0002 - Certification Procedures

Title Certification Procedures

Type Rule

59A-1.004 FAC

Regulation Definition

(1) No person shall engage in the procurement of cadaveric organs, eyes or tissues within this state without first being certified to operate by the AHCA.

Interpretive Guideline

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

(2) A dentist or physician using tissue processed by a tissue bank, but who is not involved in the retrieval, processing and distribution of tissue, is not required to be certified pursuant to these rules.
(3) All persons seeking to apply for initial or renewal certification shall submit to the AHCA a completed application, Health Care Licensing Application, Organ Procurement, Tissue Bank, Eye Bank, AHCA Form 3140-2001, July 2014, which is incorporated by reference. This form is available at: http://www.flrules.org/Gateway/reference.asp?No=Ref-05305, or http://ahca.myflorida.com/HQAlicensureforms and from the Agency for Health Care Administration, 2727 Mahan Drive, MS #32, Tallahassee, Florida 32308. An application for initial certification, including change of ownership, shall be accompanied with a check or money order in the amount of $1,000 for an OPO or tissue bank and $500 for an eye bank. Application fees shall be made payable to the AHCA and are non-refundable.
(4) Upon receipt of a completed initial application, the AHCA shall conduct an inspection or review the inspection report from an approved accreditation organization as specified in subsection 59A-1.009(2), F.A.C., to determine the applicant's compliance with the standards.
(5) A limited certificate may be issued to a tissue bank or eye bank certifying only those components of procurement which the bank has chosen to perform in Florida.
(6) A certified OPO, tissue bank or eye bank that proposes an addition in procurement services (i.e., retrieval, processing, storage or distribution) shall notify the AHCA 60 days prior to such addition. This notification shall include an explanation in the change of any aspect of the procurement process and how this change affects the agency's operations. Prior to the addition of services, the AHCA shall conduct an inspection or review the inspection report from an approved accreditation

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

organization as specified in subsection 59A-1.009(2), F.A.C., to determine if the standards of this rule are met.
(7) A certificate holder shall notify the AHCA of impending closure 90 days prior to such closure and shall be responsible for advising the AHCA as to the placement of inventory and disposition of records.

ST - B0003 - Org Rqmts - Institutional Identity

Title Org Rqmts - Institutional Identity

Type Rule

59A-1.005(1)(a) FAC

Regulation Definition

(1) Organizational Requirements.
(a) Institutional Identity.
1. The purpose of the OPO, eye bank, or tissue bank shall be clearly established and documented.
2. Documentation of institutional identity shall include whether the OPO, eye bank, or tissue bank is independent or part of another institution.
3.The OPO, eye bank, or 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.
4. Policies and procedures shall be maintained for personnel and other activities.

Interpretive Guideline

Surveyor shall review documentation for evidence that clearly states the purpose of the agency. There should be documented information regarding whether the agency is an independent operation or part of another institution.

ST - B0004 - Org Rqmts - Director/Advisory Board

Title Org Rqmts - Director/Advisory Board

Type Rule

59A-1.005(1)(b-c) FAC

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

Regulation Definition

(1) Organizational Requirements.
(b) Each OPO, eye bank, or tissue bank shall have a board of directors, an advisory board, or a designated individual to provide consultation and direction on all policy-making decisions.
(c) OPO, Eye Bank, or Tissue Bank Director. Each OPO, eye bank, or tissue bank shall have a director qualified by training and experience for the scope of activities being pursued.
1. The director shall be responsible for:
a. Development, implementation and maintenance of all procedures and policies,
b. All administrative operations including compliance with these standards,
c. The daily operation of the OPO, eye bank, or tissue bank,
d. Specifying technically acceptable means for retrieving, processing, quality control, storage, and distribution, as applies to the scope of activities being pursued,
e. Providing all staff members with adequate information to perform their duties safely and competently,
f. Appointing technical staff with capabilities and training appropriate to their function and ensuring that competency is maintained by participation in training courses and technical meetings or other educational programs. Such training shall be recorded in the employee's personnel file,
g. Establishing quality control and quality assurance programs. These programs shall include ongoing monitoring and evaluation of activities, identification of problems, and development of plans for corrective action. These procedures and records shall be reviewed at least annually; and,
h. Maintaining a working relationship with medical examiner offices in the OPO, eye bank, or tissue bank's service area.
2. If the director appointed does not have medical licensure, the OPO, eye bank, or tissue bank shall have at least one physician, employed or under contract, to ensure compliance with all medical aspects and with all requirements for

Interpretive Guideline

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

specialist knowledge of the particular organs and tissues processed.
3. The director is authorized to delegate his or her responsibilities to trained and competent staff. If responsibilities are delegated, the director remains responsible for ensuring that all duties are properly performed.

ST - B0005 - Org Rqmts - Policies/Procedures

Title Org Rqmts - Policies/Procedures

Type Rule

59A-1.005(1)(d-e) FAC

Regulation Definition

(1) Organizational Requirements.
(d) 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.
(e) Policies and Procedures. Each OPO, eye bank or tissue bank shall maintain detailed and unambiguous policies and procedures which detail all aspects of retrieval, processing, testing, storage, and distribution practices; as applicable.
1. Each of these procedures shall be reviewed and affirmed in writing annually by the director or designee.
2. Modifications of standard procedures and development of new procedures shall be approved by the director or designee prior to implementation.
3. Obsolete revised procedures shall be retained separately to maintain a historical sequence.
4. Copies of policies and procedures shall be available to the staff at all times. Technical staff shall be required to state in writing that they have read and understand the policies and procedures applicable to his or her specific responsibilities.
5. Copies of policies and procedures shall be available to

Interpretive Guideline

surveyors for inspection upon request.

ST - B0006 - Org Rqmts - Clinical Lab Testing

Title Org Rqmts - Clinical Lab Testing

Type Rule

59A-1.005(1)(f) FAC

Regulation Definition	Interpretive Guideline
(1) Organizational Requirements. (f) Clinical Laboratory Testing. Any clinical laboratory tests performed within an OPO, tissue bank or eye bank must comply with Chapter 483, F.S., and the Clinical Laboratories Improvement Act of 1988 (CLIA-88), as applicable.	

ST - B0007 - Org Rqmts - Records

Title Org Rqmts - Records

Type Rule

59A-1.005(1)(g) FAC

Regulation Definition	Interpretive Guideline
(1) Organizational Requirements. (g) Records. 1. Donor and recipient records shall be accurate, complete, and confidential as required by Section 456.057, F.S. Donor record confidentiality shall not preclude access by surveyors for the Agency when conducting an inspection or investigation pursuant to paragraphs 59A-1.009(1)(a), (b), (c), F.A.C., and the medical examiner for cases which fall within the medical examiner's jurisdiction, as established under Section 406.05, F.S. Donor medical records and final results of all laboratory tests shall be reviewed and affirmed by the medical director,	- Surveyor shall review documentation for evidence that records identify the person performing the work, including the dates of various entries, test results, and interpretation of the results.

designees, or medical contractee to ensure suitability of the donated organ(s) or tissue(s) for the intended application.
2. Documentation shall be concurrent with the performance of each activity in the retrieval, preparation, testing, storage, and distribution of organs and tissues in such a manner that all activities can be clearly traced. All records shall be legible and indelible and shall identify the person performing the procedures/tasks. The record shall include dates of entries and test results. The expiration period assigned to specific categories of processed tissues is to be recorded in the policies and procedures.
3. Records shall be as detailed as necessary for a clear understanding of each activity and shall be available for inspection by surveyors when conducting an inspection or investigation pursuant to paragraphs 59A-1.009(1)(a), (b), (c), F.A.C., upon request and within the bounds of medical-legal confidentiality, pursuant to Section 456.057, F.S.
4. Each organ donor, tissue and any components derived from tissue shall be assigned, in addition to generic designation, a unique identification number to identify the material from retrieval through distribution and utilization.
5. Records shall identify the donor, document the pathological and microbiological evaluation of the donor, verify the conditions under which the organ or tissue is retrieved, processed and stored, if applicable, and indicate disposition of the transplanted organ or tissue. Maintenance of these records shall be the responsibility of the 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 OPO, eye bank or tissue bank and its donors, persons identified by Section 765.512(3), F.S., and patient recipients shall be regarded as confidential and privileged. Surveyors shall have access to records and communication at the time of the inspection as

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

specified in Rule 59A-1.009, F.A.C.
7. Maintenance and certification records, if applicable, on facilities, instruments, and equipment, including their monitors, shall be maintained. These records shall indicate dates of inspection, name of facility, and performance evaluations. Each OPO, eye bank or tissue 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. Records of function checks requiring interpretation of findings must include the interpretation. Records must include:
a. Temperature of incubators when in use,
b. Spore lot number and expiration date used for autoclave function check; and,
c. Control and test results.
8. Each OPO, eye bank, or tissue bank shall document all aspects of its quality assurance program.
9. An adverse reactions file shall be maintained pursuant to Rule 59A-1.011, F.A.C.
10. All of these records shall be retained for seven years for OPOs and ten years for tissue banks and eye banks and be available for Agency inspection.

ST - B0008 - Safety and Environmental Control

Title Safety and Environmental Control

Type Rule

59A-1.005(2) FAC

Regulation Definition

(2) Safety and environmental control. Written procedures for the operation shall be established and approved by the director. Instructions for action in case of emergency or exposure to communicable disease, chemical and biological

Interpretive Guideline

- Surveyor shall review evidence that safety procedures and policies are posted or readily available to all personnel.
- Surveyor shall review OSHA requirements, and if there appears to be non-compliance, refer immediately to OSHA.

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

hazard precautions shall be included.
(a) Human waste items shall be disposed so as to minimize any hazard to personnel or the environment in accordance with the following rules and statutes administered by the Department of Environmental Protection and the Department of Health: Section 381.0098, F.S., Chapter 403, Part IV, F.S., and Chapter 64E-16, F.A.C.
(b) Dignified and proper disposal procedures shall be used to obviate recognizable human remains.
(c) All organs or tissues found positive for human immunodeficiency virus shall be rendered noncommunicable or shall be destroyed, unless specifically labeled to identify the human immunodeficiency virus and:
1. Is used for research purposes, or
2. Is used to save the life of another and is transferred with the recipient's informed consent.
(d) Each OPO, eye bank or tissue bank shall comply with Occupational Safety and Health Administration (OSHA) rules 29 Code of Federal Regulations (CFR) Part 1910.1030, effective April 3, 2012, which are incorporated herein by reference and available at http://www.flrules.org/Gateway/reference.asp?No=Ref-09015. These rules establish requirements for minimizing exposure to hepatitis, HIV, and other blood-borne pathogens.

ST - B0009 - Facilities and Equipment

Title Facilities and Equipment

Type Rule

59A-1.005(3) FAC

Regulation Definition

(3) Facilities and equipment.
(a) Each OPO, eye bank or tissue bank shall have established procedures regarding maintenance and acceptability

Interpretive Guideline

- Surveyor shall review for evidence of documented maintenance records.

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

guidelines.
(b) 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. All temperature measuring devices must be calibrated against National Institute of Standards and Technology (NIST) certified thermometers. Refrigerators and freezers used for the storage of tissues shall have monitors. Each OPO, eye bank or tissue bank shall have established procedures to follow in the event of electrical failure.
(c) Facility access shall be limited to employees of the OPO, eye bank or tissue bank, contractual employees of the OPO, eye bank or tissue bank, surveyors for an approved accreditation organization, and governmental surveyors as permitted by applicable laws. A security system or physical configuration shall be established to prevent entry of unauthorized persons. There shall be policies and procedures to define limited facility access. Such policies and procedures shall be made available for review by surveyors as specified in Rule 59A-1.009, F.A.C.

ST - B0010 - Ethical Standards

Title Ethical Standards

Type Rule

59A-1.005(4) FAC

Regulation Definition

(4) Ethical Standards.
(a) Each OPO, tissue bank, and eye bank shall have policies to avoid conflicts of interest. The policy shall ensure that no employee of the OPO, tissue bank or eye bank shall incur any obligation of any nature which is in substantial conflict with the full and competent performance of duties.

Interpretive Guideline

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

(b) In the event that services are provided to the procuring OPO, eye bank or tissue bank arrangements may be made to pay expenses incurred for services rendered. Reimbursement to the individual shall not be in conflict with the personnel policies of the primary employer.

ST - B0011 - Federal or Accreditation Organization

Title Federal or Accreditation Organization

Type Rule

59A-1.005(5) FAC

Regulation Definition

(5) Each OPO, eye bank or tissue bank shall provide to the Agency, upon request, a copy of any audit, review, or study performed by any federal or accreditation organization.

Interpretive Guideline

ST - B0012 - Acquisition of Organs and Tissues

Title Acquisition of Organs and Tissues

Type Rule

59A-1.005(6) FAC

Regulation Definition

(6) Acquisition of Organs and Tissues.
(a) General.
1. OPO, eye bank, or tissue bank personnel shall have written procedures to ensure that consent for donation is obtained in compliance with Chapter 765, F.S.
2. OPO, eye bank, or tissue bank personnel shall be trained regarding obtaining and documenting consent for donation.
3. Consent shall be obtained from the donor, next of kin, or other designated legal entity in order of priority and

Interpretive Guideline

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

availability according to Section 765.512, F.S.
4. A copy of the signed consent form shall remain a part of the patient's hospital medical record if signed at the hospital.
5. The original signed consent form or record of telephone consent shall be retained in the OPO, eye bank, or tissue bank's donor record.

(b) Informed Consent.
1. Permission to procure organs and tissues from donors which is obtained by informed consent shall be as defined in Rule 59A-1.003, F.A.C., and shall be documented in writing. The consent form shall include the organs and tissues for which permission is granted (e.g., bone from the upper or lower extremities or bone from below the waist). Information provided shall be written or spoken in language understandable to the donor or the donor's next of kin.
2. Permission to retrieve organs and tissues from non-living donors shall be sought from next of kin in order of legal precedence as required by Section 765.512, F.S.
3. In any cases falling under the provisions of Chapters 406 and 765, F.S., the permission of the medical examiner or appropriate designee shall be obtained prior to the procurement of any organ(s) and tissue(s). The donor records shall indicate the name of the contact person in the medical examiner's office, date and time of contact, and limitations, if any, imposed by those giving permission (e.g., DO NOT TOUCH CHEST).

ST - B0020 - Premortem Donations

Title Premortem Donations

Type Rule

59A-1.005(7) FAC

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

Regulation Definition	Interpretive Guideline
(7) Premortem donations under the Anatomical Gift Statute. Consent expressed by a living person to donate organs and tissues under provisions of the Anatomical Gift Statute, Chapter 765, Part V, F.S., are legally valid and permits organ procurement organizations, tissue banks, and eye banks to procure organs and tissues without further authorization from next of kin.	

ST - B0030 - Compensation for Donors

Title Compensation for Donors

Type Rule

59A-1.005(8) FAC

Regulation Definition	Interpretive Guideline
(8) Compensation for Donors. Monetary compensation other than reimbursement of donation-related expenses is prohibited.	

ST - B0033 - Autopsy

Title Autopsy

Type Rule

59A-1.005(9) FAC

Regulation Definition	Interpretive Guideline
(9) Autopsy. A gross external and internal examination of any area of the donor altered by the excision of organs or tissues shall be performed and dictated or otherwise recorded by the procuring person(s) at the time of the of the surgical removal. A written report of these findings shall be immediately	

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

prepared and delivered to the person(s) responsible for the autopsy of the donor. The report shall contain itemized notation of normal conditions as well as an itemization of all abnormal findings identified during the gross examination of the donor. Whenever a full medical autopsy will not be subsequently performed by a medical examiner, the medical director or designees may elect to obtain one by other means when deemed necessary. If performed, the medical director or designees shall justify and document the need for the full autopsy in the donor's medical record and shall affix a copy of the report to the donor's record.

ST - B0038 - Donor Selection Procedures

Title Donor Selection Procedures

Type Rule

59A-1.005(10) FAC

Regulation Definition

(10) Donor Selection. Each OPO,tissue bank or eye bank engaged in the retrieval or recovery of organs or tisssues, shall have written procedures regarding donor selection.
(a) The medical director or designee shall be responsible for the donor selection.
(b) Suitability of an individual for donation shall be based upon the medical history and clinical status of the donor and the need for particular organs and tissues.
(c) Criteria for evaluating a potential donor shall include presence of infectious disease, malignant disease (with specific exceptions), neurological degenerative disease, and diseases of unknown etiology or any other diseases or conditions which may be transferred to the recipient.
(d) Evaluation of the donor record shall be performed by a licensed physician or a professional familiar with the conditions for which the procured organs or tissues will be

Interpretive Guideline

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

used so that organs or tissues procured shall not be the source of any toxic or harmful effects per se when transplanted to another individual.
(e) Age of the donor shall be a consideration in the effective transplantation of certain organs or tissues but does not preclude an individual from donation.
(f) The medical director, designee, or medical contractee shall have the responsibility to document that the donor is acceptable according to the criteria established in this rule and by the procedure established by the OPO, eye bank or tissue bank.

ST - B0040 - Reconstruction

Title Reconstruction

Type Rule

59A-1.005(11) FAC

Regulation Definition

(11) Reconstruction. Each OPO, eye bank or tissue bank who is engaged in the retrieval or recovery of organs or tisssues shall have a policy for the reconstruction of the body which is integral to maintaining the dignity of the donor.

Interpretive Guideline

ST - B0042 - Quality Assurance

Title Quality Assurance

Type Rule

59A-1.005(12) FAC

Regulation Definition

(12) Quality Assurance. The quality assurance program shall include a method for the transplanting surgeon to report

Interpretive Guideline

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

adverse reactions from the transplantation of organ(s) and tissue(s) to the source OPO, tissue bank or eye bank, which in turn shall forward the adverse reaction information to the Agency as described in Rule 59A-1.011, F.A.C.

ST - B0045 - Recall Procedures

Title Recall Procedures

Type Rule

59A-1.005(13) FAC

Regulation Definition

(13) Recall Procedures. A written procedure shall exist for recall of organs or tissues or notification of recipient agencies of the possibility of contamination, defects in processing, preparation or distribution, or other factors affecting suitability of the organs or tissues for their intended application. Procedures for documenting the steps in recall or notification shall be included in the policies and procedures.

Interpretive Guideline

- Review sampling of random records to ensure that the recipient's physician and/or transplantation center are identified sufficiently to accomplish a notification or recall should such become necessary.

ST - B0048 - Look Back Procedures

Title Look Back Procedures

Type Rule

59A-1.005(14) FAC

Regulation Definition

(14) Look Back Procedures. Each OPO, tissue bank, and eye bank shall have procedures for notifying the transplanting facility or physician that they may have received infected organs or tissues. Documentation of look back procedures shall be included in the policies and procedures.

Interpretive Guideline

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

ST - B0050 - HIV Notification Requirements

Title HIV Notification Requirements

Type Rule

59A-1.005(15) FAC

Regulation Definition

(15) HIV Notification Requirements. Notification of HIV test results shall be given in accordance with the following statutes and rules administered by the Department of Health: Section 381.0041, F.S., and Rule 64D-2.005, F.A.C.

Interpretive Guideline

ST - B0052 - Data Collection

Title Data Collection

Type Rule

59A-1.005(16) FAC

Regulation Definition

(16) Data Collection. Each OPO, tissue bank, and eye bank shall collect, maintain, and report the following data annually to the Agency:
(a) Number of donors by age and race;
(b) Type of donation;
(c) Cause of death for all donors;
(d) Donor source (hospital, medical examiner, or funeral home);
(e) Number of organs retrieved and number of tissue allografts and eyes processed;
(f) Disposition of processed organs, tissues, and eyes with respect to in-state, national, or international distribution; and,
(g) Revenues derived from retrieving, processing, or

Interpretive Guideline

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

distributing organs and eye tissue, and revenues derived from retrieving, processing, storing or distributing tissues;
(h) Expenses associated with retrieving, processing, or distributing organs and eye tissue, and expenses associated with retrieving, processing, storing or distributing tissues.

ST - B0055 - Fair and Equitable System

Title Fair and Equitable System

Type Rule

59A-1.005(17) FAC

Regulation Definition

(17) Fair and Equitable System. Each OPO, eye bank, or tissue bank shall establish and document a system of distribution that is just, equitable, and fair to all patients served. Documentation of distribution (date of requests for, offer of, and delivery of organs and tissues) shall be available for examination by authorized individuals, including surveyors for the Agency. Access to organs and tissues shall be provided without regard to recipient sex, age, religion, race, creed, color or national origin.

Interpretive Guideline

- Review records for evidence that there is a documented system of distribution that is just, equitable, and fair to all patients served by the tissue bank. Documentation of distribution shall include the date of request for, offer of, and delivery of tissues.

ST - B0058 - Accreditation Organization Inspection Reports

Title Accreditation Organization Inspection Reports

Type Rule

59A-1.009(2)(a-e) FAC

Regulation Definition

(2) Acceptance of Accreditation Organization Inspection Reports.
(a) For certifying organ procurement activities, each

Interpretive Guideline

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

accredited organ procurement organization shall submit the results of each Association of Organ Procurement Organization (AOPO) inspection report and proof of accreditation or reaccreditation to the Agency within 30 days of receipt of such reports and accreditation or reaccreditation.
(b) For certifying tissue banking activities, each accredited tissue bank organization shall submit the results of each American Association of Tissue Banks (AATB) inspection report and proof of accreditation or reaccreditation to the Agency within 30 days of receipt of such reports and accreditation or reaccreditation.
(c) For certifying eye bank activities, each accredited eye bank shall submit the results of each Eye Bank Association of America (EBAA) inspection report and proof of accreditation or reaccreditation to the Agency within 30 days of receipt of such reports and accreditation or reaccreditation.
(d) If the certified organization voluntarily forfeits its accreditation by AOPO, AATB or EBAA, if the accreditation is suspended or terminated, or if the certified organization is denied accreditation or re-accreditation by any of these accrediting organizations, the certified organization must provide written notification to the AHCA within 30 days of the forfeiture or denial.
(e) Failure to submit the required accreditation inspection report and final determination or written notification of forfeiture, suspension, termination or denial of accreditation shall be considered a failure to submit to an inspection and will result in administrative action as provided in Chapter 408, Part II, F.S. and these rules.

ST - B0060 - Annual Reporting Requirements

Title Annual Reporting Requirements

Type Rule

59A-1.009(4-8) FAC

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

Regulation Definition

(4) Each certified agency shall submit to the AHCA its most recently completed annual audit within 30 days after the anniversary date of certification.
(5) Each certified OPO shall submit to the AHCA the Annual Report for Organ Procurement, Distribution, Revenues and Expenses, AHCA Form 3140-2002-APR 2008, incorporated herein by reference and available at: http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Laboratory_Licensure/organ.shtml, within 30 days after the anniversary date of certification.
(6) Each certified tissue bank shall submit to the AHCA the Annual Report for Tissue Procurement, Distribution, Revenues and Expenses, AHCA Form 3140-2004-DEC 2008, incorporated herein by reference and available at: http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Laboratory_Licensure/organ.shtml, within 30 days after the anniversary date of certification.
(7) Each certified eye bank shall submit to the AHCA the Annual Report for Eye Procurement, Distribution, Revenues and Expenses, AHCA FORM 3140-2005-DEC 2008, incorporated herein by reference and available at: http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Laboratory_Licensure/organ.shtml, within 30 days after the anniversary date of certification.
(8) These forms shall be available on the Agency website at: www.licensing_cert.shtml, or from the Agency for Health Care Administration, Division of Health Quality Assurance, Laboratory Licensure Unit, 2727 Mahan Drive, MS #32, Tallahassee, Florida 32308. The data to be submitted to the AHCA are described in subsection 59A-1.005(17), F.A.C. All reported donor information shall be based on the previous calendar year. All revenue and expense information shall be based on the most recently completed fiscal or operational year.

Interpretive Guideline

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

ST - B0062 - Adverse Reactions

Title Adverse Reactions

Type Rule

59A-1.011(1) FAC

Regulation Definition	Interpretive Guideline
(1) General. 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. It is the responsibility of each physician and organization that utilizes organs and tissues for transplantation to notify the providing organ procurement organization, tissue bank, or eye bank in writing of any and all adverse reactions with regard to transmission of infections or other diseases. The providing organization shall notify the medical examiner if the adverse reaction involves donation from a medical examiner'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 follow-up (e.g., pre-addressed follow-up cards, a toll free number, etc.) to report such instance.	

ST - B0064 - Adverse Reactions - Notification

Title Adverse Reactions - Notification

Type Rule

59A-1.011(2) FAC

Regulation Definition	Interpretive Guideline
(2) Notification of adverse reaction. (a) In accordance with subsection 59A-1.005(14), F.A.C.,	

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

each agency shall, upon notification of an adverse reaction by a transplanting physician or hospital:
1. Immediately notify the Agency for Health Care Administration, Division of Health Quality Assurance, by telephone of a potential 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 organs and tissues; and
4. Submit to the Agency for Health Care Administration, Division of Health Quality Assurance, within two working days, Part I of the AHCA's Organ and Tissue Adverse Reaction Reporting Form, AHCA Form 3140-2003-OCT 95. This entire form is incorporated herein by reference and available from the Agency for Health Care Administration, Division of Health Quality Assurance, Ft. Knox Office Building, 2727 Mahan Drive, Tallahassee, Florida 32308.

ST - B0066 - Adverse Reactions - Followup Procedures

Title Adverse Reactions - Followup Procedures

Type Rule

59A-1.011(3) FAC

Regulation Definition

(3) Follow-up procedures.
(a) Where it is determined that the adverse reaction was due to the donor organs and tissues, each agency shall institute recall procedures in accordance with subsection 59A-1.005(15), F.A.C., and look back procedures in accordance subsection 59A-1.005(16) F.A.C.
(b) Once a final determination of the cause of an adverse reaction is made, each agency shall submit Part II of the AHCA's Organ and Tissue Adverse Reaction Reporting Form, AHCA Form 3140-2003-OCT 95, to the Division of Health

Interpretive Guideline

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

Quality Assurance.

ST - B0070 - Deny, Revoke, Suspend, Fine

Title Deny, Revoke, Suspend, Fine

Type Rule

59A-1.012(1) FAC

Regulation Definition

(1) Depending upon the seriousness of the violation, the AHCA shall deny, revoke, or suspend a certificate or impose an administrative fine not to exceed $500 per day per violation for any of the following actions:
(a) Making false statements on an application or on any document associated with certification;
(b) Advertising false services or credentials;
(c) Failing to pay within 30 days of assessment, trust fund assessments in accordance with Section 765.544, F.S.;
(d) Failing to comply with the provisions of Chapter 59A-1, F.A.C.;
(e) Failing to correct deficiencies within the time required by the AHCA;
(f) Failing to submit an annual income statement and annual data on organ and tissue procurement, revenues and expenses specified in subsection 59A-1.005(17), F.A.C.;
(g) Failing to inform the AHCA of an adverse reaction or failing to comply with all provisions of Rule 59A-1.011, F.A.C.;
(h) Violating or aiding and abetting in the violation of any other provision of these regulations or the rules promulgated thereunder; or
(j) Violating an agency moratorium as described in Rule 59A-1.012, F.A.C.

Interpretive Guideline

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

ST - B0075 - Rights and Duties at Death

Title Rights and Duties at Death

Type Rule

765.517(2-4) FS

Regulation Definition

(2) The time of death shall be determined by a physician who attends the donor at the donor's death or, if there is no such physician, the physician who certifies the death. After death, those physicians or the donor's primary care physician may participate in, but may not obstruct, the procedures to preserve the donor's organs or tissues and may not be paid or reimbursed for such participation, nor be associated with or employed by, a procurement organization. These physicians may not participate in the procedures for removing or transplanting a part. However, this subsection does not prevent a physician from serving in a voluntary capacity on the board of directors of a procurement organization or participating on any board, council, commission, or similar body related to the organ and tissue procurement system.
(3) The procurement organizations, or hospital medical professionals under the direction thereof, may perform any and all tests to evaluate the deceased as a potential donor and any invasive procedures on the deceased body in order to preserve the potential donor's organs. These procedures do not include the surgical removal of an organ or penetrating any body cavity, specifically for the purpose of donation, until:
(a) It has been verified that the deceased's consent to donate appears in the donor registry or a properly executed document of gift is located; or
(b) If a properly executed document of gift cannot be located or the deceased's consent is not listed in the donor registry, a person specified in s. 765.512(2) or (3) has been located, has

Interpretive Guideline

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

been notified of the death, and has granted legal permission for the donation.
(4) All reasonable additional expenses incurred in the procedures to preserve the donor's organs or tissues shall be reimbursed by the procurement organization.

ST - B0077 - Duties and Liability

Title Duties and Liability

Type Rule

765.522(1) & (7) FS

Regulation Definition

(1) If, based on accepted medical standards, a hospital patient is a suitable candidate for organ or tissue donation, the hospital administrator or the hospital administrator's designee shall, at or near the time of death, notify the appropriate procurement organization, which shall access the donor registry created by s. 765.5155 or any other donor registry to ascertain the existence of an entry in the registry which has not been revoked or a document of gift executed by the decedent. In the absence of an entry in the donor registry, a document of gift, or other properly executed document, the procurement organization shall request:
(a) The patient's health care surrogate, as authorized in s. 765.512(2); or
(b) If the patient does not have a surrogate, or the surrogate is not reasonably available, any of the persons specified in s. 765.512(3), in the order and manner listed,
to consent to the anatomical gift of the decedent's body for any purpose specified in this part. Except as provided in s. 765.512, in the absence of actual notice of opposition, consent need only be obtained from the person or persons in the highest priority class reasonably available.

Interpretive Guideline

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

(7) The hospital administrator or a designee shall, at or near the time of death of a potential donor, directly notify the affiliated organ procurement organization of the potential organ donor. The organ procurement organization must offer any organ from such a donor first to patients on a Florida-based local or state organ sharing transplant list. For the purpose of this subsection, the term "transplant list" includes certain categories of national or regional organ sharing for patients of exceptional need or exceptional match, as approved or mandated by the Organ Procurement and Transplantation Network, or its agent. This notification may not be made to a tissue bank or eye bank in lieu of the organ procurement organization unless the tissue bank or eye bank is also designated as an organ procurement organization.

ST - B0079 - Rqmts to Engage in Organ/Tissue/Eye Procureme

Title Rqmts to Engage in Organ/Tissue/Eye Procureme

Type Rule

765.542(1-3) FS

Regulation Definition

(1) The requirements of part II of chapter 408 apply to the provision of services that require licensure pursuant to ss. 765.541-765.546 and part II of chapter 408 and to entities licensed or certified by or applying for such licensure or certification from the agency pursuant to ss. 765.541-765.546. A person may not engage in the practice of organ procurement in this state without being designated as an organ procurement organization by the Secretary of the United States Department of Health and Human Services and being appropriately certified by the agency. A physician or organ procurement organization based outside this state is exempt from these certification requirements if:
(a) The organs are procured for an out-of-state patient who is

Interpretive Guideline

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

listed on, or referred through, the United Network for Organ Sharing System; and
(b) The organs are procured through an agreement of an organ procurement organization certified by the state.
(2) A person may not engage in tissue procurement in this state unless it is appropriately certified as a tissue bank by the agency.
(3) A person may not engage in the practice of eye procurement in this state without being appropriately certified as an eye bank by the agency. Funeral directors or direct disposers who retrieve eye tissue for an eye bank certified under this subsection are exempt from the certification requirements under this subsection.

ST - B0080 - Cadaveric Organ and Tissue Procurement

Title Cadaveric Organ and Tissue Procurement

Type Rule

765.545 FS

Regulation Definition

Procurement organizations may employ coordinators who are registered nurses, physician's assistants, or other medically trained personnel who meet the relevant standards for procurement organizations adopted by the agency under s. 765.541, to assist in the medical management of organ donors or in the surgical procurement of cadaveric organs, tissues, or eyes for transplantation or research. A coordinator who assists in the medical management of organ donors or in the surgical procurement of cadaveric organs, tissues, or eyes for transplantation or research must do so under the direction and supervision of a physician medical director pursuant to rules and guidelines adopted by the agency. With the exception of organ procurement surgery, this supervision may be indirect supervision. For purposes of this section, the term "indirect

Interpretive Guideline

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

supervision" means that the medical director is responsible for the medical actions of the coordinator, that the coordinator is operating under protocols expressly approved by the medical director, and that the medical director or his or her physician designee is always available, in person or by telephone, to provide medical direction, consultation, and advice in cases of organ, tissue, and eye donation and procurement. Although indirect supervision is authorized under this section, direct physician supervision is to be encouraged when appropriate.

ST - B0082 - Cadaveric Organs / Out-of-State Physicians

Title Cadaveric Organs / Out-of-State Physicians

Type Rule

765.546 FS

Regulation Definition

Any physician currently licensed to practice medicine and surgery in the United States may surgically procure in this state cadaveric organs for transplant if:
(1) The organs are being procured for an out-of-state patient who is listed on, or referred through, the United Network for Organ Sharing System; and
(2) The organs are being procured through the auspices of an organ procurement organization certified in this state.

Interpretive Guideline

ST - BE600 - Federal Compliance

Title Federal Compliance

Type Rule

59A-1.005(45-46) FAC

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

Regulation Definition

(45) Each eye bank shall comply with 21 C.F.R. Part 1270, 2010 Edition, and 21 C.F.R. Part 1271, 2012 Edition.
(46) Each eye bank shall be registered as a tissue establishment with the U.S. Food and Drug Administration (FDA) as required by 21 C.F.R. Part 1271.21.

Interpretive Guideline

ST - BE602 - Eye Bank Organization Staff Requirements

Title Eye Bank Organization Staff Requirements

Type Rule

59A-1.005(47) FAC

Regulation Definition

(47) Eye Bank Organization Staff Requirements.
(a) The medical director shall have served a corneal fellowship, and shall be certified by the American Board of Ophthalmology.
(b) Eye Bank technical personnel.
1. 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 ensure 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.
2. An eye bank technician shall be trained in acquisition, evaluation, processing, storage and distribution of eye tissue for transplantation.
3. A procurement technician shall be proficient in screening and retrieval of the eye tissue.

Interpretive Guideline

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

ST - BE604 - Training/Certification/Continuing Education

Title Training/Certification/Continuing Education

Type Rule

59A-1.005(48) FAC

Regulation Definition

(48) Training, Certification, and Continuing Education.
(a) An eye bank shall provide an orientation program for each new technician and the employee's participation shall be documented.
(b) An eye bank shall provide educational opportunities such as in-service 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.
(c) To function as the supervisory technician in the eye bank processing laboratory, the technician must pass the Eye Bank Association of America's (EBAA) Technician Certification examination or an approved examination administered by a medical school's Department of Ophthalmology approved for residency training in ophthalmology.

Interpretive Guideline

ST - BE606 - Performance Standards

Title Performance Standards

Type Rule

59A-1.005(49) FAC

Regulation Definition

(49) Performance Standards.
(a) Each eye bank shall demonstrate proficiency in all aspects

Interpretive Guideline

of eye banking by annually retrieving, processing, or distributing at least 100 corneas for penetrating keratoplasty and provide the Agency with documentation of its performance upon request.
(b) 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 all available records on each eye donor shall be performed by an individual who is qualified by profession, education and training to do so, and who is familiar with the intended use of the tissue.

ST - BE608 - Eye Donor Selection

Title Eye Donor Selection

Type Rule

59A-1.005(50) FAC

Regulation Definition

(50) Eye Donor Selection.
(a) Eye tissue from donors with the following shall not be used for penetrating keratoplasty, lamellar keratoplasty, patch grafts, epikeratoplasty or any other type of surgery:
1. Death of unknown cause;
2. Death from central nervous system diseases of unknown etiology;
3. Creutzfeldt-Jakob disease;
4. Subacute sclerosing panencephalitis;
5. Progressive multifocal leukoencephalopathy;
6. Congenital rubella;
7. Reye's syndrome;
8. Active viral encephalitis of unknown origin;
9. Active septicemia (bacteremia, fungemia, viremia);
10. Active bacterial or fungal endocarditis;

Interpretive Guideline

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

11. Active viral hepatitis;
12. Rabies;
13. Intrinsic eye disease:
a. Retinoblastoma;
b. Malignant tumors of the anterior ocular segment;
c. Active ocular or intraocular inflammation: conjunctivitis, scleritis, iritis, uveitis, vitreitis, choroiditis, retinitis;
d. Congenital or acquired disorders of the eye which would preclude a successful outcome for the intended use, e.g., a central donor corneal scar for an intended penetrating keratoplasty, keratoconus, and keratoglobus; and,
e. Pterygia or other superficial disorders of the conjunctiva or corneal surface involving the central optical area of the corneal button.
f. Exceptions are that tissue with local eye disease affecting the corneal endothelium may be used for epikeratoplasty, patch grafts, and scleral transplant surgery, and tissue with local eye disease affecting the corneal endothelium or previous ocular surgery that does not compromise the corneal stroma may be used for lamellar keratoplasty or patch grafts.
14. Prior intraocular or anterior segment surgery:
a. Refractive corneal procedures, e.g., radial keratotomy, lamellar inserts, etc.;
b. Laser photoablation surgery;
c. If corneas are used from donors who have had prior anterior segment surgery (e.g., cataract, intraocular lens, glaucoma filtration), the corneas shall be screened by specular microscopy and meet the eye bank's endothelial standards as determined by the medical director; and,
d. Laser surgical procedures such as argon laser trabeculoplasty, retinal and panretinal photocoagulation do not necessarily preclude use for penetrating keratoplasty but shall be cleared by the medical director.
15. Active leukemia;
16. Active disseminated lymphomas;

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

17. Hepatitis B surface antigen positive donors;
18. Recipients of human pituitary-derived growth hormone (pit-hGH) during the years from 1963-1985;
19. HIV seropositive donors;
20. Acquired immunodeficiency syndrome (AIDS);
21. Children (under 13 years old) and infants of mothers with AIDS or at high risk of HIV infection;
22. High risk for HIV infection based on the FDA Guidance Concerning Application of Testing and High Risk Criteria for HIV and Hepatitis for Banked Human Tissue, incorporated herein by reference.
23. HTLV infection except in the case of viable, leukocyte cell or tissue donors;
24. Active syphilis; and,
25. Hepatitis C seropositive donors.
(b) Tissue from donors meeting the criteria in paragraph 59A-1.005(50)(a), F.A.C., above shall not be used for epikeratoplasty or other surgery with the exception that tissue with local eye disease affecting the corneal endothelium (e.g., aphakia, iritis) is acceptable for use. Interval of time from donor's death to preservation of eye tissue may be extended.

ST - BE610 - Eye Donor Testing

Title Eye Donor Testing

Type Rule

59A-1.005(51) FAC

Regulation Definition

(51) Eye Donor Testing.
(a) Microbiologic Culturing. Culturing of eye bank donor eyes is recommended. However, the responsibility for determining the need for culturing shall reside with the transplanting surgeon.
1. Presurgical Cultures. Eye banks may elect to perform

Interpretive Guideline

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

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. Surgical Culturing. 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.
(b) HIV Screening.
1. Each eye bank shall have an HIV screening program using FDA-approved tests, pursuant to Rule 64D-2.005, F.A.C., for all donors of surgically designated tissue. A negative screening test shall be documented prior to release of tissue for transplantation.
2. Eye tissue from a donor who has been transfused shall comply with the FDA Guidance for Industry "Eligibility Determination for Donors of Human Cells, Tissues and Cellular and Tissue-based Products (HCT/Ps)", August 2007.
(c) 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.
(d) 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.
(e) HTLV Screening. HTLV screening is required of viable, leukocyte rich cells or tissues only. If donor screening for HTLV has been performed, a negative screening test shall be obtained and documented prior to release of tissue for

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

transplantation.
(f) Syphilis Screening. If the screening test is performed and is positive, a negative confirmatory test shall be obtained and documented prior to release of tissue for transplantation.

ST - BE612 - Documentation of Eye Donor Information

Title Documentation of Eye Donor Information

Type Rule

59A-1.005(52) FAC

Regulation Definition

(52) Documentation of Eye Donor Information.
(a) Donor screening forms and copies of medical charts, medical examiner, or coroner review forms and gross autopsy results, if performed, shall be completed and retained on all donated eye tissue as part of the donor record. Until the final written autopsy report becomes available, documentation of verbal reports of autopsy findings are acceptable.
(b) 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 surveyors for the Agency. The record shall include the following minimum information:
1. Eye bank identification number unique to each tissue graft;
2. Name of eye bank;
3. Location of eye bank;
4. Phone number;
5. Type of preservation;
6. Age of donor;

Interpretive Guideline

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

7. Cause of death;
8. Death date and time;
9. Enucleation or in-situ retrieval date and time;
10. Preservation date and time;
11. Slit lamp report;
12. Specular microscopy, if performed;
13. Name of enucleator/evaluator/technician;
14. Name of surgeon receiving tissue;
15. Recipient identification;
16. Utilization of non-transplantable tissue;
17. All serological or microbiological tests performed; and,
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/implantation.

ST - BE614 - Facilities and Equipment

Title Facilities and Equipment

Type Rule

59A-1.005(53) FAC

Regulation Definition

(53) Eye Bank Facilities and Equipment.
(a) 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) Each eye bank shall have an adequate stable electrical source and a sufficient number of grounded electrical outlets for operating laboratory equipment. Laminar flow hoods or similar piece of equipment shall be available for sterile processing.
(c) Each eye bank shall have a refrigerator with a device for recording temperature variations. Temperature variations shall be recorded daily and remain within the range of 2 degrees to

Interpretive Guideline

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

6 degrees C. These records shall be kept for a minimum of ten 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, i.e., quarantined tissue, surgical tissue awaiting distribution, and research tissue.
(d) In the event of a power failure, there shall be established policies and procedures for action to be taken, which may include an emergency power supply to maintain essential refrigeration.
(e) No sterilized instruments, supplies, and reagents, such as corneal preservation medium for surgical tissues, shall be used beyond the expiration date for surgical tissues.

ST - BE616 - Satellite Eye Banks

Title Satellite Eye Banks

Type Rule

59A-1.005(54) FAC

Regulation Definition

(54) Satellite Eye Banks. Satellite eye banks that retrieve, process, and distribute tissue shall have a technician and be supervised by and have access to a qualified medical director or designee. Such satellite eye bank shall be inspected by surveyors for the Agency as part of the certification process for the parent eye bank.

Interpretive Guideline

ST - BE618 - Eye Bank Retrieval/Processing Procedures

Title Eye Bank Retrieval/Processing Procedures

Type Rule

59A-1.005(55) FAC

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

Regulation Definition

(55) Eye Bank Retrieval and Processing Procedures.
(a) Enucleation procedure. Ultimate responsibility for personnel who perform enucleation rests with the director and the medical director.
(b) In-situ and facility-based removal of the corneal-scleral rim. Removal of the corneal-scleral rim shall be performed using sterile technique by individuals specifically trained in in-situ retrieval and facility-based removal of the corneal-scleral segment.
(c) Use of preservation medium. Eye banks shall use a corneal storage medium which has been used and stored according to the manufacturer's recommendations. The manufacturer's recommendations must be retained and made available for inspection by surveyors for the Agency.
(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. If the eye bank preserves scleral tissue, the selected preservation method shall be documented in the eye bank's own procedures manual.
2. An expiration date for use of tissue shall be indicated based on the container capability and 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

Interpretive Guideline

- Surveyor reviews documentation for manufacturer's recommendation for storage and usage of the medium available in the laboratory.

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

means of storage of the body. Corneal preservation shall occur as soon as possible after death and within the time frame determined by the medical director as defined by the policies and procedures. All time intervals (i.e., time of death to the time of enucleation and preservation) 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 policies and procedures. 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 criteria established in this rule.
(j) Non-surgical donor tissue. If donor tissue is provided for purposes other than surgery, e.g., research, practice surgery, etc., and if that donor tissue is not screened for 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 and transport.

ST - BE620 - Eye Tissue Evaluation

Title Eye Tissue Evaluation

Type Rule

59A-1.005(56) FAC

Regulation Definition

(56) Eye Tissue Evaluation. The transplanting surgeon has ultimate responsibility for determining the suitability of the tissue for transplantation.

Interpretive Guideline

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

(a) Gross examination. The corneal-scleral segment shall be initially examined grossly for clarity, epithelial defects, foreign objects, contamination, and scleral color (e.g., jaundice).
(b) Slit lamp 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 and corneal retrieval. After corneal retrieval, the corneal-scleral rim shall be evaluated by slit lamp biomicroscopy, even if the donor eye has been examined with the slit lamp prior to retrieval of the corneal-scleral rim, to ensure that damage to the corneal endothelium or surgical detachment of Descemet's membrane did not occur.

ST - BE622 - Eye Tissue Storage

Title Eye Tissue Storage

Type Rule

59A-1.005(57) FAC

Regulation Definition

(57) Eye Tissue Storage.
(a) All surgical tissue shall be stored in quarantine until negative serology results have been documented, in accordance with the following rule administered by the Department of Health: Rule 64D-2.005, F.A.C.
(b) All tissue shall be stored at a temperature appropriate to the method of preservation used.
(c) Each eye bank shall precisely document its procedures for storage.

Interpretive Guideline

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

ST - BE624 - Corneal or Scleral Tissue Labeling

Title Corneal or Scleral Tissue Labeling

Type Rule

59A-1.005(58) FAC

Regulation Definition	Interpretive Guideline
(58) Corneal or Scleral Tissue Labeling. (a) Visual inspection. A sufficient area of the container shall remain unobstructed to permit inspection of the contents. (b) Each corneal or scleral tissue shall be clearly and indelibly labeled to include, at least, the following: 1. Name of source eye bank; 2. Tissue identification number; 3. Type of tissue; 4. Date and time of donor's death; 5. Date and time of corneal-scleral preservation; 6. Expiration date for scleral tissue; and, 7. A statement shall accompany the tissue stating that: a. The tissue is intended for single patient application only and that it is not to be considered sterile and that the FDA therefore recommends culturing or reculturing; and, b. The tissue has undergone infectious disease testing.	

ST - BE626 - Eye Tissue Packaging

Title Eye Tissue Packaging

Type Rule

59A-1.005(59) FAC

Regulation Definition	Interpretive Guideline
(59) Eye Tissue Packaging.	- The shrink wrap covers the cap and half the vial.

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

(a) Each tissue shall be individually packaged and sealed with a shrink wrap.
(b) The tissue shall be packed in a water proof 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.
(c) 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. That the surgeon shall check for integrity of the seal and immediately report to the eye bank any evidence of possible tampering;
3. That color change per the manufacturer's guidelines may indicate a change in pH, in which case the tissue shall not be used and a report made immediately to the eye bank;
4. Whether pre-surgical microbiological cultures were performed by the eye bank, including the advisement that culture of the donor rim and sclera shall be performed at the time of surgery; and,
5. The form shall also advise 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.

ST - BO200 - Federal Compliance

Title Federal Compliance

Type Rule

59A-1.005(18) FAC

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

Regulation Definition

(18) Each OPO shall comply with 42 CFR Parts 413, 441, 486, and 498, effective May 31, 2006, incorporated herein by reference and available at http://www.flrules.org/Gateway/reference.asp?No=Ref-09014. Records relating to the federal standards must be made available upon request.

Interpretive Guideline

ST - BO202 - OPTN Membership

Title OPTN Membership

Type Rule

59A-1.005(19) FAC

Regulation Definition

(19) Each OPO shall be a member in good standing of the Organ Procurement Transplantation Network (OPTN) created by 42 CFR Part 121.

Interpretive Guideline

ST - BO204 - Medical Director

Title Medical Director

Type Rule

59A-1.005(20-21) FAC

Regulation Definition

(20) Each OPO shall employ or have under contract a physician medical director who:
(a) Is licensed to practice medicine in the state of Florida;
(b) Is board certified in a specialty recognized by the American Board of Medical Specialties (ABMS); and,
(c) Has a minimum of two (2) years affiliation with an OPO,

Interpretive Guideline

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

transplant program or tertiary care hospital associated with a transplant program.
(21) The Medical Director of an OPO shall provide direction and supervision to coordinators and all other staff who assist in the procurement of organs for transplantation. With the exception of organ recovery surgery, this may be indirect supervision.

ST - BO206 - Financial Policies and Procedures

Title Financial Policies and Procedures

Type Rule

59A-1.005(22) FAC

Regulation Definition

(22) Financial Policies and Procedures.
(a) The OPO shall have accounting and other fiscal procedures necessary to ensure the fiscal stability of the organization, including procedures to obtain payment for kidneys and non-renal organs provided to transplant centers.
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. In the case of hospital OPOs, the hospital must undergo an annual financial audit.
3. There shall be adequately 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 assets, liabilities and fund balance, and statements of its periodic revenues and expenses. Hospital OPOs shall be

Interpretive Guideline

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

exempt from this requirement to the extent that these functions are performed by hospital staff.
(b) 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) 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. Hospital OPOs shall adhere to an appropriate hospital authority for established accounting policies and procedures.
(d) 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(s), the cost shall be allocated only to that organ(s).
(e) The accounting records of the OPO shall permit the expensing of indirect costs, (e.g., office rent, utilities, administrative salaries and salary related costs) so that they may be allocated in compliance with Medicare rules and guidelines.
1. The OPO's costs shall be charged as expenses and allocated in accordance with the appropriate guidance provided by the Medicare program or by the appropriate hospital authority for hospital OPOs and by established agreements with other agencies, companies, providers or vendors.
2. The costs paid by the OPO for services used in the

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

procurement of organs (for example, surgeon's fees, donor evaluation fees, laboratory, transportation, etc.) shall be based on reasonable and customary fees within the service area as determined by the OPO. The OPO may refer to limitations on the reimbursement of such costs as specified by the Medicare program.
(f) 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 semi-annually and appropriate adjustments made unless otherwise proscribed.

ST - BO208 - Verification of Death

Title Verification of Death

Type Rule

59A-1.005(23) FAC

Regulation Definition

(23) Verification of Death. The OPO shall ensure that death has been determined in accordance with traditional cardiopulmonary criteria or as required by Section 382.009, F.S., and documented in the organ donor's medical record.

Interpretive Guideline

ST - BO210 - Donor Evaluation/Management Procedures

Title Donor Evaluation/Management Procedures

Type Rule

59A-1.005(24) FAC

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

Regulation Definition

(24) An OPO's policies and procedures for the evaluation and management of a potential organ donor shall be in writing. Evaluation and management of donors is mandatory for organs which may be allocated to and received by the Organ Procurement and Transplantation Network (OPTN)-approved transplant programs to ensure that all organ donors meet the minimum standards and the requirements established by the OPTN policies, effective April 6, 2017, incorporated herein by reference and available at http://www.flrules.org/Gateway/reference.asp?No=Ref-09009.
(a) The OPO's organ donor evaluation and management procedures shall be approved by the OPO's medical director.
(b) Once the patient has been declared dead or death is imminent and consent for donation has been obtained from the next of kin and from the medical examiner, if the death meets the requirements for referral to the medical examiner as specified in Chapter 406, F.S., the OPO shall implement the guidelines for the evaluation and management of the potential organ donor.
(c) 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; and,
5. Documentation of significant events in the donor's clinical course.
(d) In the brain dead donor, the OPO shall ensure that adequate respiratory, hemodynamic and electrolyte management of the donor is provided.
(e) The OPO shall ensure that the donor receives appropriate antibiotic coverage, if a need is indicated.

Interpretive Guideline

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

(f) The OPO shall evaluate the infectious disease status of the potential donor. All serological testing shall be noted to be either pre- or post-transfusion. Such evaluation shall include:
1. Hepatitis testing according to OPTN policies and procedures;
2. Appropriate FDA-licensed HIV-1/HIV-2 screens;
3. Serologic test for syphilis (STS);
4. Blood and urine cultures;
5. Cytomegalovirus (CMV); and,
6. Complete blood count (CBC).

ST - BO212 - Allocation of Donated Organs

Title Allocation of Donated Organs

Type Rule

59A-1.005(25) FAC

Regulation Definition

(25) Allocation of Donated Organs.
(a) Each OPO shall have a policy to ensure that donated organs are allocated according to OPTN policies, effective April 6, 2017.
(b) The OPO shall document that the OPTN computer was accessed and reason for selection of a donor/recipient match and the placement allocation of the donor organ.
(c) Organs shall be allocated by the OPO utilizing the sequence of patients as determined by OPTN computer.
(d) Documentation of actual allocation of each organ procured shall be filed in accordance with OPTN policies, effective April 6, 2017.

Interpretive Guideline

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

ST - BO214 - Procurement Procedures

Title Procurement Procedures

Type Rule

59A-1.005(26)(a-e) FAC

Regulation Definition

(26) Procurement Procedures. The OPO shall have written policies and procedures to facilitate and coordinate the recovery of donated organs by trained and qualified personnel.
(a) A certified HHS OPO shall ensure that any surgeons (i.e., surgeons whose fees are paid by the OPO) working as consultants to the OPO for the surgical recovery of donated organs meet qualifications and standards as set by the OPO's medical director.
(b) The medical director of the OPO shall be responsible for the surgical standards.
(c) The OPO is responsible for coordinating anesthesia support for the organ procurement process. The OPO shall provide protocols to the anesthesia support service for the intra-operative procedure which address:
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; and,
4. Administration of required and desirable medications to facilitate organ procurement and function.
(d) If the anesthesia records are not included in the donor's chart, records reflecting documentation of anesthesia protocol used by the OPO shall be available for inspection.
(e) In all organ donors, the OPO is responsible for packaging and labeling organs, tissue typing material and blood, according to OPTN policies, effective April 6, 2017.

Interpretive Guideline

- Review documentation for evidence of information/guidelines for the administration of anesthesia for the intra-operative procedure.

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

ST - BO216 - Procurement Procedures - Documents

Title Procurement Procedures - Documents

Type Rule

59A-1.005(26)(f) FAC

Regulation Definition

(26) Procurement Procedures. The OPO shall have written policies and procedures to facilitate and coordinate the recovery of donated organs by trained and qualified personnel.
(f) In all organ donors, 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. Copy of death determination from the donor's medical record;
3. Copy of consent for organ procurement from the donor's medical record; and,
4. Copy of the following OPO donor information:
a. 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. The OPO shall have a standardized method of recording the following information on each donor:
(I) Name;
(II) Age, sex, race;
(III) Cause of death;
(IV) Time and date of hospital admission;
(V) Time and date of pronouncement of death;
(VI) United Network for Organ Sharing (UNOS) identification number; and,

Interpretive Guideline

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

(VII) OPO identification number.
c. The OPO shall document the following information for purposes of follow-up:
(I) Name and address of the legal next of kin;
(II) Record of the organs donated;
(III) Name of attending and consulting doctor;
(IV) Medical examiner or coroner, as applicable;
(V) Copy of signed consent form; and,
(VI) Copy of declaration of death note.
d. Documentation of donor history. The OPO shall obtain a medical and social history of each potential donor in an attempt to determine whether the potential donor is at increased risk as described in "PHS Guideline for Reducing Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Transmission Through Organ Transplantation", as published in Public Health Reports/July-August 2013/Volume 128, incorporated herein by reference and available online at: http://www.flrules.org/Gateway/reference.asp?No=Ref-09010. That history shall be communicated to the physician responsible for the care of the recipient.
e. The documented past medical history shall, when available, include significant episodes of the following:
(I) Any previous hospitalization;
(II) Any prior surgery;
(III) History of a chronic illness, e.g., diabetes, hypertension, cardiovascular disease, etc.;
(IV) History of communicable disease, e.g., hepatitis; and,
(V) History of disease specific to transplantable organs and treatment of same.
f. The current hospital history is the most vital and shall include:
(I) Description of injuries and treatments (e.g., surgeries);
(II) Account of significant febrile episodes - duration, treatment, and response;

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

(III) Account of cardiac and pulmonary arrests - type, duration, and all treatment required to restore function (particularly closed chest massage); and,
(IV) Record of blood transfusions - type and amount.
g. Documentation of donor hemodynamics.
h. Documentation of blood pressures shall include:
(I) Average pressure;
(II) Any hypotensive periods - noting lowest pressure and duration;
(III) Use of vasopressors - type, amount, duration, and response;
(IV) Any periods of prolonged hypertension - highest pressure, duration, and treatment instituted;
(V) Any abnormal heart rhythm and treatment; and,
(VI) Swan Ganz and central venous pressure readings and which shall be correlated with blood pressure, when available.
i. Transfused donor. All potential donors are to be tested for HIV-1/HIV-2 antibodies in accordance with the following rule administered by the Department of Health: Rule 64D-2.005, F.A.C. If the donor's pre-transfusion test is antibody negative and subsequent transfusions are pre-tested, retesting for HIV-1/HIV-2 antibodies is not necessary. If no pre-transfusion 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 (10) day period immediately prior to removal of the organs. Except as provided in Section 59A-1.005(2)(c), F.A.C., organs from donors with repeatedly reactive screening tests for HIV-1/HIV-2 antibodies are not suitable for transplantation unless subsequent confirmation testing unequivocally indicates that the original test result was unconfirmed. If additional tests related to HIV-1/HIV-2 antibodies are performed, the results of all tests must be communicated immediately to the recipient's institution.

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

ST - BO218 - Documentation of Organ-Specific Test Results

Title Documentation of Organ-Specific Test Results

Type Rule

59A-1.005(27) FAC

Regulation Definition

(27) Documentation of Organ-Specific Test Results. Requirements for organ specific testing shall be in writing. The OPO shall provide the transplanting physician with certain test results for the evaluation of organ function. These results shall be documented in a standardized manner.
(a) The OPO shall, at minimum, document the following available lab results for ALL donors:
1. CBC;
2. Electrolytes;
3. ABO typing;
4. Blood and urine cultures;
5. Serological testing in accordance with OPTN policies, effective April 6, 2017;
6. Appropriate FDA-licensed HIV-1/HIV-2 screens. If blood products have been given, a pre-transfused sample shall be obtained. If unavailable, explanation shall be documented in the donor's medical record;
7. Cultures, including blood, and urine, which allow for interpretation of laboratory results. Each OPO must define procedures for the type, source and indication for obtaining these cultures;
8. CMV antibody.
(b) Kidney evaluation:
1. Urinalysis;
2. Creatinine; and,
3. Blood urea nitrogen (BUN).
(c) Liver evaluation:

Interpretive Guideline

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

1. Liver enzymes;
2. Total bilirubin;
3. Direct bilirubin; and,
4. Prothrombin time/partial thromboplastin time (PT/PTT).
(d) Heart evaluation:
1. 12 lead EKG;
2. Cardiology consult;
3. Chest X-ray;
4. Blood gases;
5. Echocardiogram or cardiac cath (optional); and,
6. Creatine phosphokinase including MB fraction.
(e) Pancreas evaluation:
1. Serum amylase;
2. Serum lipase; and,
3. Glucose.
(f) Lung evaluation:
1. Blood gases;
2. Chest X-ray; and,
3. Sputum gram stain and culture.
(g) The OPO shall utilize an internal standard format or form to document all of the above-mentioned information.

ST - BO220 - Volume Intake/Urine Output Documentation

Title Volume Intake/Urine Output Documentation

Type Rule

59A-1.005(28) FAC

Regulation Definition

(28) The OPO shall document detailed information on volume intake and urine output in order to assess and maintain donor stability.
(a) The OPO shall document volume intake type (crystalloid vs. colloid) and amount for a minimum of 8 hours prior to organ procurement and for the duration of the operative

Interpretive Guideline

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

procedure. The use of any blood or blood products shall be noted.
(b) The OPO shall document urine output for a minimum of 8 hours prior, if possible, to organ retrieval and for the duration of the operative procedure. Any periods of oliguria, anuria, or the occurrence of diabetes insipidus and its treatment shall be documented.

ST - BO222 - Documentation of Organ Retrieval Procedure

Title Documentation of Organ Retrieval Procedure

Type Rule

59A-1.005(29) FAC

Regulation Definition

(29) Documentation of Organ Retrieval Procedure.
(a) The OPO is responsible for proper documentation of intraoperative information and all information related to the surgical recovery of all organs for transplantation.
(b) Documentation shall include:
1. Blood pressures, urine output, and fluids administered;
2. Medications administered;
3. Blood products administered;
4. Type and amount of perfusion solution and flush characteristics;
5. Type of storage solution;
6. Type of procurement procedure (i.e., enbloc, in-situ perfusion);
7. Aortic cross-clamp time and date;
8. Description of typing material available;
9. Warm ischemia time;
10. Anatomical description:
a. Kidneys - include number of vessels and approximate length and diameter of each;
b. Extra renal - include description and any injuries or

Interpretive Guideline

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

abnormalities; and,
11. Organs recovered and not utilized. If the organs are not used for transplantation or research, a written note regarding disposition shall be documented in the OPO's donor records.

ST - BO224 - Documentation of Organ Recipient Information

Title Documentation of Organ Recipient Information

Type Rule

59A-1.005(30) FAC

Regulation Definition	Interpretive Guideline
(30) Documentation of Organ Recipient Information. (a) The OPO shall document specific information on the recipients of recovered organs. (b) The following information shall be documented on each recipient: 1. Name; 2. A recipient identification number; 3. Recipient center; and, 4. Age, sex, and race.	- Review records for documentation that the information is available on each recipient.

ST - BO225 - Discrimination in access to anatomical gifts

Title Discrimination in access to anatomical gifts

Type Rule

765.523(2-7) FS

Regulation Definition	Interpretive Guideline
(2) A covered entity may not do any of the following solely on the basis of an individual's disability: (a) Consider a qualified individual ineligible to receive an anatomical gift or organ transplant.	

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

(b) Deny medical or other services related to an organ transplant, including evaluation, surgery, counseling, and posttransplant treatment and services.
(c) Refuse to refer the individual to an organ procurement organization or a related specialist for the purpose of evaluation or receipt of an organ transplant.
(d) Refuse to place a qualified individual on an organ transplant waiting list.
(e) Place a qualified individual at a lower priority position on an organ transplant waiting list than the position at which the qualified individual would have been placed if not for the disability.
(3)(a) A covered entity may take an individual's disability into account if, following an individualized evaluation of him or her, a physician finds the individual's disability to be medically significant to the provision of the anatomical gift or organ transplant, but only to the extent that the covered entity is making treatment or coverage recommendations or decisions for the individual.
(b) If an individual has the necessary support system to assist him or her in complying with posttransplant medical requirements, a covered entity may not consider the individual's inability to independently comply with the posttransplant medical requirements to be medically significant for the purposes of paragraph (a).
(4) A covered entity shall make reasonable modifications to policies, practices, or procedures when the modifications are necessary to allow an individual with a disability access to services, including transplant-related counseling, information, coverage, or treatment, unless the covered entity can demonstrate that making the modifications would fundamentally alter the nature of the services. Such modifications shall include, but need not be limited to, communication with the persons responsible for supporting the individual with his or her postsurgical and posttransplant

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

care, including medication. Such modifications shall also consider the support networks available to the individual, including, but not limited to, family, friends, and home and community-based services coverage when determining whether the individual is able to comply with posttransplant medical requirements.
(5) A covered entity shall take such steps as may be necessary to ensure that an individual with a disability is not denied services, including transplant-related counseling, information, coverage, or treatment, due to the absence of auxiliary aids and services, unless the covered entity can demonstrate that taking the steps would fundamentally alter the nature of the services being offered or would result in an undue burden on the covered entity.
(6) If a covered entity violates this section, the qualified individual who is affected by the violation may bring an action in the appropriate circuit court for injunctive or other equitable relief.
(7) This section may not be construed to require a covered entity to make a referral or recommendation for or perform a medically inappropriate organ transplant.

ST - BT400 - Federal Compliance

Title Federal Compliance

Type Rule

59A-1.005(31-32) FAC

Regulation Definition

(31) Each tissue bank shall comply with 21 CFR Part 1270, 2010 Edition, which is incorporated herein by reference and available at http://www.flrules.org/Gateway/reference.asp?No=Ref-09011 and 21 C.F.R. Part 1271, 2012 Edition which is incorporated herein by reference and available at

Interpretive Guideline

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

http://www.flrules.org/Gateway/reference.asp?No=Ref-09012
and make the records demonstrating compliance with the federal standards available to surveyors for the Agency.
(32) Each tissue bank shall be registered as a tissue establishment with the U.S. Food and Drug Administration (FDA) as required by 21 C.F.R. Part 1271.21.

ST - BT402 - Tissue Bank Organizational Staff Requirements

Title Tissue Bank Organizational Staff Requirements

Type Rule

59A-1.005(33) FAC

Regulation Definition

(33) Tissue Bank Organizational Staff Requirements.
(a) Each tissue bank shall employ or have under contract a physician medical director who maintains a valid state license from any state within the United States.
(b) Medical directors are required to assure that no actual or potential conflict of interest occurs when acting as Medical Director for multiple tissue banks.
(c) Qualifications of technical personnel vary by nature of responsibility. Qualifications may be demonstrated by certification by examination administered by the American Association of Tissue Banks.
(d) All supervisory or senior technical personnel responsible for performing retrieval or processing activities shall be certified in tissue banking by the American Association of Tissue Banks within 18 months of employment with a licensed tissue bank.

Interpretive Guideline

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

ST - BT404 - Tissue Donor Selection

Title Tissue Donor Selection

Type Rule

59A-1.005(34) FAC

Regulation Definition

(34) Tissue Donor Selection.
(a) The eligibility of each donor must be determined by a licensed Medical Director using all available relevant information. Such determination shall be documented.
(b) A medical history shall be examined, if available. If scant medical history is available, as in the case of a sudden death, a documented attempt shall be made to acquire information beyond what is available 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 the release in the donor's medical record.
(c) HIV infections. HIV testing shall be performed in accordance with the following rule administered by the Department of Health: Rule 64D-2.005, F.A.C.
(d) Tissues with evidence of infectious diseases are conditions which shall preclude distribution for transplantation. The following is a list of examples of commonly encountered conditions which preclude donation of tissues:
1. Infectious diseases such as:
a. Septicemia (demonstrable) at time of death;
b. Systemic mycoses;
c. Meningitis or encephalitis;
d. Active systemic viral disease or past history of chronic viral disease;
e. Active tuberculosis;
f. Active or chronic hepatitis of viral or unknown etiology;

Interpretive Guideline

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

and,
g. Active syphilis or anatomically demonstrable syphilitic lesions.
2. Bacterial infections such as:
a. Pyelonephritis associated with sepsis or systemic infection;
b. Gross Peritonitis or abdominal abcess (not only microscopic inflammation);
c. Pneumonia associated with sepsis or systemic infection;
d. Bacterial endocarditis;
e. Osteomyelitis; and,
f. Other potentially transmittable bacterial diseases.
3. Malignancies. Individuals with malignancies arising anywhere in the body shall be excluded from the donor pool. Any exceptions shall be approved by the medical director.
4. Collagen and immune complex diseases determined by the Medical Director to impact the specific tissues to be distributed such as:
a. Rheumatoid arthritis;
b. Systemic lupus erythematosus;
c. Polyarteritis nodsa;
d. Sarcoidosis;
e. Myasthenia gravis; and,
f. Acute rheumatic fever.
5. Transfused Donor. Tissues from a donor who has been transfused shall comply with the FDA Guidance for Industry "Eligibility Determination for Donors of Human Cells, Tissues and Cellular and Tissue-based Products (HCT/Ps)," August 2007, incorporated herein by reference and available at http://www.flrules.org/Gateway/reference.asp?No=Ref-09016.
6. Recipients of organ transplants. Recipients of organ transplants shall not be automatically eliminated because of the transplant.
7. Other. Toxic exposure sufficient to affect tissue procured and an unknown but suspicious medical history shall constitute a reason for rejecting a donor.

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

ST - BT406 - Required Studies of the Tissue Donor

Title Required Studies of the Tissue Donor

Type Rule

59A-1.005(35) FAC

Regulation Definition

(35) Required studies of the tissue donor in addition to FDA requirements specified in Rule 59A-1.005, F.A.C.
(a) Serologies:
1. HBcAb;
2. FDA-licensed HTLV test for viable, leukocyte rich cells or tissues only;
3. Serologic test for syphilis (STS) - confirmed. Tissues from donors with positive (confirmed) tests shall not be used for transplantation; and,
4. Rh determination shall be provided cautioning about the possibility of sensitization.
(b) Evaluation of the 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 donation.

Interpretive Guideline

ST - BT408 - Microbiological Examination

Title Microbiological Examination

Type Rule

59A-1.005(36) FAC

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

Regulation Definition	Interpretive Guideline
(36) Microbiological Examination. Each tissue bank shall have written microbiological laboratory policies and procedures which, at minimum, ensure allograft safety. Documentation of adherence to these policies and procedures is required.	

ST - BT410 - Tissue Bank Records

Title Tissue Bank Records

Type Rule

59A-1.005(37) FAC

Regulation Definition	Interpretive Guideline
(37) Tissue Bank Records. (a) Responses from transplant centers which identify adverse reactions attributable to allografts shall be maintained. The records of the tissue bank shall be open to inspection by the Agency at a mutually convenient time. (b) Records shall show the expiration date assigned to specific processed tissues as defined in the policies and procedures. (c) 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 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. (d) A tissue bank, when sending tissue to a hospital or surgeon, must request in writing that the transplanting surgeon report allograft-related complications to the tissue bank's	

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

medical director. Records of adverse reactions and all related follow-up documentation shall be maintained for a period of ten years.
(e) Inventory. A record of all unprocessed, processed, and distributed tissues shall be maintained.

ST - BT412 - Documentation of Tissue Donor Information

Title Documentation of Tissue Donor Information

Type Rule

59A-1.005(38) FAC

Regulation Definition

(38) Documentation of Tissue Donor Information. The records shall include all information on the donor including laboratory reports, autopsy reports, a clinical history, a tissue procurement record, donor eligibility and related material. The records of the consent to procure the tissue are kept at least ten (10) years after the date of its administration, or if the date of its administration is not known, at least ten (10) years after the date of distribution, disposition, or expiration, whichever is later.

Interpretive Guideline

ST - BT414 - Timely Procurement

Title Timely Procurement

Type Rule

59A-1.005(39) FAC

Regulation Definition

(39) Timely Procurement. The tissue bank shall have written procedures that specify the time limits for the recovery of tissue consistent with tissue-specific standards, where

Interpretive Guideline

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

applicable.

ST - BT416 - Tissue Bank Facilities and Equipment

Title Tissue Bank Facilities and Equipment

Type Rule

59A-1.005(40) FAC

Regulation Definition	Interpretive Guideline
(40) Tissue Bank Facilities and Equipment. Environmental monitoring procedures shall be established in writing as part of the quality assurance program, when applicable. Monitoring procedures for processing tissue, at minimum, shall include equipment and personnel monitoring where tissue contact occurs, work-surface cultures, and, where appropriate, static and dynamic air particulate air sampling.	- View the operating room to ensure the presence of air filtration, stainless steel furniture, washable walls, etc.

ST - BT418 - Tissue Retrieval and Processing Procedures

Title Tissue Retrieval and Processing Procedures

Type Rule

59A-1.005(41) FAC

Regulation Definition	Interpretive Guideline
(41) Tissue Retrieval and Processing Procedures. (a) Tissues shall be retrieved using either aseptic or clean, nonsterile techniques. If tissues are retrieved using aseptic techniques, methods shall be consistent with standard operating room practice. Aseptic technique does not necessarily preclude the need for subsequent tissue sterilization. Allografts procured using aseptic or clean, nonsterile techniques are suitable for transplantation if adequate precautions are taken to identify and eliminate	

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

microorganisms.
(b) Tissue banks employing ethylene oxide (ETO) for sterilization of tissues, chambers of freeze-dryers, instruments or equipment must monitor occupational exposure to ethylene oxide. Semi-annual reports of ETO monitoring must be kept for 30 years. Specifically the following requirements must be met and documented:
1. Air change rate - minimum rate for rooms where ethylene oxide is used is 10 air changes per hour.
2. Review of gas circuits. The following must be checked for leaks:
a. Gas tank valves;
b. Gas tank manifolds including filter cartridges;
c. Sterilizer and other equipment door seals;
d. Pressure relief valves;
e. Gas-steam mixing chambers;
f. All elbows, compression fittings, gauges, valves, etc. along the gas circuit;
g. Gas inlet into chamber; and,
h. Chamber air intake filter.
3. ETO alarm must be installed near equipment where ETO spill may be possible.
4. Automatic aeration after sterilization without having to open sterilizer door must be provided.
5. Periodic personnel exposure monitoring must be conducted.
6. A canister type respirator (NIOSH approved and rated for 5,000 ppm ETO) and gloves must be kept in the gas sterilization area in case of an emergency.
7. Safety data sheets must be kept in the tissue bank and the location of these sheets and content must be known to the employee.
8. An emergency evacuation plan must be posted for all employees to see.
9. Personnel must be trained regarding the safe use of ETO and records retained in the file.

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

10. All exhaust systems must be non-circulating.
(c) 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. Each type of tissue shall be processed according to written tissue bank procedures.
(d) Bone and tissue allografts shall be packaged in an environment specified in written procedures.

ST - BT420 - Tissue Labeling

Title Tissue Labeling

Type Rule

59A-1.005(42) FAC

Regulation Definition

(42) Tissue Labeling.
(a) Container label. Containers shall be labeled so as to identify the following:
1. Name of the product;
2. Name and address of the tissue bank;
3. Tissue identification number; and,
4. Expiration date, if applicable.
(b) Shipping label. Packages shall be labeled so as to identify the following:
1. Identification of human tissue;
2. Name and address of tissue bank;
3. Name of facility to which tissue is being shipped;
4. Recommended storage temperature; and,
5. Special instructions indicated by the particular product, e.g., DO NOT FREEZE.

Interpretive Guideline

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

ST - BT422 - Tissue Shipping

Title Tissue Shipping

Type Rule

59A-1.005(43) FAC

Regulation Definition	Interpretive Guideline
(43) Tissue Shipping. (a) Each tissue bank shall have written procedures for shipping. (b) Packaging shall be designed to ensure tissue quality and prevent contamination of the contents of the final container(s). (c) 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. Such instructions shall include: 1. Presence of known sensitizing substances; 2. Type of antibiotics present, if applicable; 3. A statement that it has undergone infectious disease testing; 4. Sterilization procedure, if utilized; and, 5. Concentration of preservative(s) and/or cryoprotectant(s) in final package solution, if applicable.	- Visibly inspect several packaged bone and tissue allografts using a magnifying glass to determine if these may contain any foreign matter and to determine the adequacy of washing.

ST - BT424 - Tissue Tracking

Title Tissue Tracking

Type Rule

59A-1.005(44) FAC

Regulation Definition	Interpretive Guideline
(44) Tissue Tracking.	

Aspen State Regulation Set: B 2.01 Organ, Tissue and Eye

(a) Each tissue bank shall have written procedures for tissue tracking.
(b) Each tissue and any components derived therefrom shall be assigned, in addition to generic designation, one unique tissue identification number which shall identify the material during all steps from retrieval through distribution and utilization.