Database of State Statutes

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DATABASE OF STATE STATUTES APPLICABLE TO PERMITTING, LICENSING, AUTHORIZATION AND REGISTRATION OF TISSUE BANKS AND ORGAN PROCUREMENT ORGANIZATIONS IN STATES IN WHICH AATB-ACCREDITED TISSUE ESTABLISHMENTS OPERATE

This database is a compendium of state statutory provisions relating to the permitting, licensing, certification and/or registration of tissue banks and organ procurement organizations in states in which AATB-accredited tissue establishments have their headquarters or main corporate office. The database is intended to serve as a convenient starting point for identifying such provisions.

Users of this database should understand its limitations.

- The database is not intended to, and does not, provide legal advice, and you should not rely upon it for that purpose. If you desire legal advice concerning the application of, and compliance with, the provisions included in the database or any other, you should consult with an attorney.
- The database is not intended to constitute instruction on how to obtain a permit, certification, license or registration in a particular state.
- The database contains the actual text of the provisions included herein, as of May 26, 2017, the date this database was prepared, and a live link to each such code provision; the linked provision may or may not reflect revisions made by states to their code provisions subsequent to May 26, 2017. Although this database may be updated in the future, users should check the actual state code to determine whether the language of a particular provision has been repealed, supplemented or otherwise amended or revised.
- The database does not include summaries or interpretations of such provisions.
- The database does not cover (1) states in which no AATB-accredited tissue bank operates, (2) states where AATB-accredited establishments operate only through satellite offices (i.e., where no AATB-accredited establishment maintains its headquarters or main corporate office), (3) federal (U.S.) statutes and regulations, or (4) the statutes, laws or regulations of any other country.
- States in which AATB-accredited banks operate but that do not have statutory provisions relating to permitting, licensing, authorization or registration have been included in the database with a corresponding notation of “N/A”.
- The database addresses only the statutory requirements for obtaining a permit, certification, license or registration in a particular state. It does not include statutory or regulatory provisions relating to other requirements, e.g., operational or reporting requirements.
- The database includes reprints of provisions from various state statutes, but it does not include regulations found in the regulatory codes of the covered states. You should consider applicable provisions of state regulatory codes, if any, which are not included here.
- Terms used in the re-printed statutory provisions may be defined elsewhere in the particular state code or in corresponding regulatory codes. Such definitions will influence the proper interpretation of the statutory provision to which it relates.
- Although the database includes some definitions, in most cases applicable definitions have not been included. Users of the database should identify and consider such definitions.
- Terms used in statutory provisions included in this database do not necessarily have the same meaning as given to
the same, or similar, terms in AATB’s 14th edition of Standards.

- For further information on requirements and procedures relating to obtaining a permit, certification, license or registration, you may want to consult with state agencies having jurisdiction over such matters, e.g., a department of licensing and permitting, or a department of health.
- There may be penalties for operating a tissue establishment without complying with an applicable requirement relating to permitting, licensing, authorization or registration. The database does not identify such penalty provisions, if any.

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§ 22-19-122. Promulgation of proficiency standards and quality assurance measures; certification to acquire and transport organs, etc.; updating of quality assurance standards.

(a) The Chairman of the Department of Surgery of the School of Medicine at the University of Alabama at Birmingham is authorized to establish and promulgate the standards of proficiency and fitness and measures and procedures for quality assurance in the acquiring and/or transporting of organs, bones, and tissues retrieved in Alabama.

(b) The Chairman of the Department of Surgery of the School of Medicine at the University of Alabama at Birmingham shall certify when a person shall be allowed to acquire and/or transport any organ, bone or tissue retrieved in Alabama. The chairman shall not certify any person to acquire and/or transport any organ, bone or tissue to be retrieved in Alabama until such person possesses and demonstrates to the chairman the necessary knowledge and technical skills to comply with the established standards of proficiency and fitness.

(c) After the chairman establishes and promulgates the initial standards of quality assurance, any proposed subsequent updating, except to meet federal standards, are to be circulated for comment only, to any institution in Alabama then performing organ transplants. The chairman shall still have the final and sole decision to establish and promulgate whatever is appropriate for updating the standards of quality assurance.

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<td>§ 36–851.01. Procurement organizations; licensure; renewal; fees; penalties; exceptions [2]</td>
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A. A person may not act as a procurement organization in this state unless the person is licensed by the department of health services as a procurement organization. The person shall apply in writing to the director of the department on a form specified by the director, shall include all information requested in the application and shall pay the fees prescribed by the director.

B. The director shall grant a procurement organization license to a person if the organization either is accredited by a nationally recognized accrediting agency that is approved by the department of health services and maintains full accreditation with the accrediting agency or meets the requirements prescribed in section 36–851.03 and the rules adopted by the department.

C. A license under this section is valid for two years and must be renewed every two years. A person shall file an application for renewal at least thirty days before the expiration of the current license.

D. Each procurement organization applying for licensure or license renewal under this section shall pay all applicable fees as prescribed by the director. All fees collected pursuant to this section for the licensure and license renewal of procurement organizations shall be deposited in the health services licensing fund established by section 36–414.

E. The director may sanction, impose civil penalties on or, pursuant to title 41, chapter 6, article 10, suspend or revoke, in whole or in part, the license of any procurement organization if any person who is an owner, officer, agent or employee of the procurement organization is in or continues to be in violation of this article.
or the rules of the department of health services adopted pursuant to this article.

F. This section does not apply to any of the following:

1. An organ procurement organization as described by 42 United States Code section 273 that is designated for this state by the secretary of the United States department of health and human services pursuant to 42 United States Code section 1320b–8.

2. A procurement organization that is regulated by the United States food and drug administration in connection with the recovery of human tissue intended for transplantation pursuant to 21 Code of Federal Regulations part 1270.

3. A procurement organization as defined in section 36–841, paragraph 23, subdivision (d).

4. A procurement organization that is affiliated with an accredited educational institution in connection with the education of students enrolled in a degree-granting program for health professionals.

5. A procurement organization that recovers anatomical gifts for research, or education, including for quality improvement or quality assurance and that is affiliated with a hospital that is licensed pursuant to chapter 4 of this title.

6. A hospital that is licensed pursuant to chapter 4 of this title.

Cal. Health & Safety Code § 1635.1

Definitions, Licensure, and Exceptions

(a) Except as provided in subdivision (b), every tissue bank operating in California on or after July 1, 1992, shall have a current and valid tissue bank license issued or renewed by the department pursuant to Section 1639.2 or 1639.3.

(b) This chapter does not apply to any of the following:

1. The collection, processing, storage, or distribution of human whole blood or its derivatives by blood banks licensed pursuant to Chapter 4 (commencing with Section 1600) or any person exempt from licensure under that chapter.

2. The collection, processing, storage, or distribution of tissue for autopsy, biopsy, training, education, or for other medical or scientific research or investigation, when transplantation of the tissue is not intended or reasonably foreseeable.

3. The collection of tissue by an individual physician and surgeon from his or her patient or the implantation of tissue by an individual physician and surgeon into his or her patient. This exemption shall not be interpreted to apply to any processing or storage of the tissue, except for the processing and storage of semen by an individual physician and surgeon when the semen was collected by that physician and surgeon from a semen donor or obtained by that physician and surgeon from a tissue bank licensed under this chapter.

4. The collection, processing, storage, or distribution of fetal tissue or tissue derived from a human embryo or fetus.

5. The collection, processing, storage, or distribution by an organ procurement organization (OPO), as defined in Section 486.302 of Title 42 of the Code of Federal Regulations, if the OPO, at the time of collection, processing, storage, and distribution of the tissue, has been designated by the Secretary of Health and Human Services as an OPO and meets the requirements of Sections 486.304 and 486.306 of Title 42 of the Code of Federal Regulations, as applicable.

6. The storage of prepackaged, freeze-dried bone by a general acute care hospital.

7. The storage of freeze-dried bone and dermis by any licensed dentist practicing in a lawful practice setting, if the freeze-dried bone and dermis have been obtained from a licensed tissue bank, are stored in strict accordance with a kit's package insert and any other manufacturer instructions and guidelines, and are used for the express purpose of implantation into a patient.

8. The storage of a human cell, tissue, or cellular- or tissue-based product (HCT/P), as defined by the
federal Food and Drug Administration (FDA), that is either a medical device approved pursuant to Section 510 or 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 360 et seq.) or that is a biologic product approved under Section 351 of the federal Public Health Service Act (42 U.S.C. Sec. 262) by a licensed physician or podiatrist acting within the scope and authority of his or her license and practicing in a lawful practice setting. The medical device or biologic product must have been obtained from a California-licensed tissue bank, been stored in strict accordance with the device’s or product’s package insert and any other manufacturer instructions, and used solely for the express purpose of direct implantation into or application on the practitioner’s own patient. In order to be eligible for the exemption in this paragraph, the entity or organization where the physician or podiatrist who is eligible for the exemption is practicing shall notify the department, in writing, that the practitioner is licensed and meets the requirements of this paragraph. The notification shall include all of the following:

(A) A list of all practitioners to whom the notice applies.

(B) Acknowledgment that each listed practitioner uses the medical device or biologic product in the scope and authority of his or her license and practice for the purposes of direct patient care as described in this paragraph.

(C) A statement that each listed practitioner agrees to strictly abide by the directions for storage in the device’s or product’s package insert and any other manufacturer instructions and guidelines.

(D) Acknowledgment by each practitioner that the medical device or biologic product shall not be resold or distributed.

(9) The collection, processing, storage, or distribution of any organ, as defined in paragraph (2) of subdivision (c) of Section 1635, within a single general acute care hospital, as defined in subdivision (a) of Section 1250, operating a Medicare-approved transplant program.

(10) The storage of allograft tissue by a person if all of the following apply:

(A) The person, as defined in Section 1635, is a hospital, or an outpatient setting regulated by the Medical Board of California pursuant to Chapter 1.3 (commencing with Section 1248), including an ambulatory surgical center.

(B) The person maintains a log that includes the date on which the allograft tissue was received, the expiration date of the allograft tissue, the date on which each allograft tissue is used for clinical purposes, and the disposition of any allograft tissue samples that remain unused at the time the allograft tissue expires.

(C) The allograft tissue meets all of the following:

(i) The allograft tissue was obtained from a tissue bank licensed by the state.

(ii) Each allograft tissue is individually boxed and labeled with a unique identification number and expiration date so that opening the shipping container will not disturb or otherwise alter any of the allograft tissue that is not being utilized.

(iii) The allograft tissue is intended for the express purpose of implantation into or application on a patient.

(iv) The allograft tissue is not intended for further distribution.

(v) The allograft tissue is registered with the FDA and designated to be maintained at ambient room temperature requiring no refrigeration.
licenses to operate and maintain hospitals for humans pursuant to Chapter 5 of Title 44.

(b) The Council of the District of Columbia is authorized, after public hearing, to adopt and promulgate rules and regulations to carry out the purposes of this subchapter and subchapter II-A of this chapter, including, without limitation, rules and regulations prescribing:

1. The terms and conditions under which a tissue bank license may be issued and renewed;

2. The fees to be paid for the issuance and renewal of such licenses;

3. The duration of such licenses;

4. The grounds for suspension and revocation of such licenses;

5. The operation of tissue banks;

6. The conditions under which tissue may be recovered, screened, tested, processed, stored, distributed, and transported; and

7. The making, keeping, and disposition of records by tissue banks or by other persons recovering, screening, testing, processing, storing, distributing, or transporting tissue.

c) The Mayor may, after notice and hearing, deny, suspend, or revoke any tissue bank license issued or applied for pursuant to this subchapter and §§ 43-119 and 43-125.

d) Any person aggrieved by any final decision or final order of the Mayor denying, suspending, or revoking any tissue bank license or renewal thereof, issued or applied for under this subchapter and §§ 43-119 and 43-125, may obtain a review of such decision or order in the District of Columbia Court of Appeals.

e) Except with respect to the provisions as to licensing, the provisions of this subchapter and §§ 43-119 and 43-125, and the regulations made pursuant thereto, shall apply to federal agencies situated in the District of Columbia, and to District of Columbia agencies.

F.S.A. § 765.541  [5]

Certification of procurement organizations; agency responsibilities

The agency[2] shall:

1. Establish a program for the certification of organizations, corporations, or other entities engaged in the procurement of organs, tissues, and eyes for transplantation.

2. Adopt rules that set forth appropriate standards and guidelines for the program in accordance with ss. 765.541-765.546 and part II of chapter 408. These standards and guidelines must be substantially based on the existing laws of the Federal Government and this state and the existing standards and guidelines of the United Network for Organ Sharing (UNOS), the American Association of Tissue Banks (AATB), the South-Eastern Organ Procurement Foundation (SEOPF), the North American Transplant Coordinators Organization (NATCO), and the Eye Bank Association of America (EBAA). In addition, the agency shall, before adopting these standards and guidelines, seek input from all procurement organizations based in this state.

3. Collect, keep, and make available to the Governor and the Legislature information regarding the numbers and disposition of organs, tissues, and eyes procured by each certified procurement organization.

4. Monitor procurement organizations for program compliance.

5. Provide for the administration of the Organ and Tissue Procurement and Transplantation Advisory Board.

F.S.A. § 765.542  [5]

Requirements to engage in organ, tissue, or eye procurement

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 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.

(4) 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. The agency may issue a limited certificate if it determines that the tissue bank or eye bank is adequately staffed and equipped to operate in conformity with the rules adopted under this section.

§ 31-22-1. [6]
Definitions
...

(2) “Clinical laboratory” means a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the diagnosis of, recommendation of treatment of, or for the purposes of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings; the term “clinical laboratory” shall include specimen collection stations and shall include blood banks which provide through their ownership or operation a system for the collection, processing, or storage of human blood and its component parts as well as tissue banks which procure, store, or process human or animal tissues designed to be used for medical purposes in human beings. The term “clinical laboratory” shall not include laboratories which are nondiagnostic only and regulated pursuant to the federal Clinical Laboratory Improvement Amendments (CLIA) whose sole function is to perform examination of human blood or blood components intended as source material for the manufacture of biological products.

§ 31-22-2. [7]
Licenses

(a) No clinical laboratory shall be operated without a license issued and in force pursuant to this chapter; provided, however, that the department may promulgate rules and regulations by which a facility or a part of a facility in which laboratory testing is done may qualify for exemption from licensure when only specific tests or techniques, designated by the department and used for screening and monitoring purposes only, are performed.

(b) Application for licenses shall be made to the Department of Community Health on forms prescribed by it. The application shall indicate the categories of procedures to be performed and shall contain such additional information as the department may require. Each application shall be accompanied by a nonrefundable fee prescribed by the department.

(c) The license applied for shall be issued if the department finds that all requirements are met or, in the case of a new clinical laboratory not yet in operation, that the owner is in a position to meet them. A license shall authorize the performance of one or more procedures or categories of procedures and shall be valid for one year from the date of issue unless sooner canceled, suspended, or revoked.

(d) A clinical laboratory license may be denied, revoked, suspended, limited, or renewal thereof denied on
the following grounds:

(1) Making false statements of material information on an application for clinical laboratory license or any other documents required by the department;

(2) Permitting unauthorized persons to perform technical procedures or to issue or sign reports;

(3) Demonstrating incompetence in the performance or reporting of clinical laboratory examinations and procedures;

(4) Performing a test for or rendering a report to a person not authorized by law to receive such services;

(5) Referring a specimen for examination to a clinical laboratory in this state which has not been licensed pursuant to this chapter unless such referral laboratory is exempted from coverage of this chapter;

(6) Making a report on clinical laboratory work actually performed in another clinical laboratory without designating the name of the director and the name and address of the clinical laboratory in which the test was performed;

(7) Lending the use of the name of the licensed clinical laboratory or its personnel to an unlicensed clinical laboratory;

(8) Violating or aiding in the violation of any provision of this chapter or the rules or regulations promulgated hereunder; or

(9) Violating any other provisions of law applicable to the proper operation of a clinical laboratory.

(e) Each clinical laboratory shall have a licensed director. An individual shall be permitted to direct no more than three clinical laboratories. No individual shall function as a director of a clinical laboratory unless he is a physician licensed to practice medicine and surgery pursuant to Chapter 34 of Title 43; provided, however, that the director of a clinical laboratory restricting its practice to dental pathology may be either a physician licensed to practice medicine and surgery or a dentist licensed to practice dentistry; provided, further, that the board may promulgate rules and regulations which authorize persons who possess doctorate degrees in biology, microbiology, and related fields to be directors of clinical laboratories when the proper circumstances and qualifications are present.

(f) A clinical laboratory license shall specify on the face thereof the names of the owner and director, procedures or categories of procedures authorized, the location at which such procedures are to be performed, and the period for which the license is valid. The license shall be displayed at all times in a prominent place where it may be viewed by the public.

(g) Licenses issued pursuant to this chapter shall be subject to renewal in accordance with rules and regulations of the department.

(h) The board shall fix and publish in print or electronically and from time to time revise schedules of fees for applications and renewals. Such fees for clinical laboratory licenses shall be in amounts calculated to defray the costs of necessary inspections, evaluations, and investigations related thereto.

(i) The board shall promulgate rules and regulations which specify minimum standards for laboratory supervisors; provided, however, that nothing in this chapter shall be construed to affect any director, supervisor, technologist, or technician who is holding any such position on July 1, 1970.

(j) For the purposes of licensure, specimen collection stations which have a parent clinical laboratory licensed by the State of Georgia may be considered by the department to be part of that laboratory.

20 ILCS 2310/2310-330

Sperm and tissue bank registry; AIDS test for donors; penalties.

(a) The Department shall establish a registry of all sperm banks and tissue banks operating in this State. All sperm banks and tissue banks operating in this State shall register with the Department by May 1 of
each year. Any person, hospital, clinic, corporation, partnership, or other legal entity that operates a sperm bank or tissue bank in this State and fails to register with the Department pursuant to this Section commits a business offense and shall be subject to a fine of $5000.

(d) For the purposes of this Section:

“Human tissue” shall not be construed to mean organs or whole blood or its component parts.

“Tissue bank” has the same meaning as set forth in the Illinois Anatomical Gift Act.

The Secretary of the Department of Health and Hospitals “shall compile and disseminate a list of those nonprofit organ and tissue banks that, in addition to the Louisiana designated OPO, shall be authorized to receive donations under this Section. The organ procurement organization shall be authorized upon designation by the Health Care Finance Administration.

The nonprofit tissue bank or eye bank must submit copies of the following to the secretary for authorization:

1. proof that a nonprofit tissue bank or eye bank registered in this state or any state as a 501-C-3 charitable organization with no direct ties to any for-profit tissue processor unless an approved nonprofit vehicle is unavailable;

2. a copy of the current accreditation letter by the American Association of Tissue Banking for those nonprofit tissue banks, and a current accreditation letter by the Eye Banks of America Association for the nonprofit eye banks.

A person shall hold a permit issued by the Secretary before the person may:

(1) Operate a tissue bank in this State; or

(2) Represent or service in this State any tissue bank that is outside this State.

To qualify for a permit, an applicant shall satisfy the Secretary that the tissue bank to be operated, represented, or serviced and its director meet the requirements that the Secretary adopts under this subtitle.

The Secretary shall adopt rules and regulations that set qualifications for directors of tissue banks.
Technical, medical directors

(b) The rules and regulations shall require that a tissue bank in this State employ or retain under contract:

(1) A technical director, qualified by training and experience for the scope of activities being pursued, who will oversee and be responsible for all technical aspects of the tissue bank's operations; and

(2) A medical director who will be a physician licensed to practice medicine in this State and who will be responsible for all medical aspects of the tissue bank's operations, unless the technical director qualifies as a medical director under this section.

MD Code, Health - General, § 17-307. [13]

Permit Applications

(a) An applicant for a permit shall submit an application to the Secretary on the form that the Secretary requires.

Contents

(b)(1) An application for a permit to operate a tissue bank shall include:

(i) The name of the owner;

(ii) The classes of services that the tissue bank would provide; and

(iii) Any other information that the Secretary requires.

(2) An application for a permit to represent or service a tissue bank shall include satisfactory evidence that the tissue bank to be represented or serviced and its director meet the requirements that the Secretary adopts under this subtitle.

Fees

(c) The applicant shall pay to the Department the application fee set by the Secretary.

MD Code, Health - General, § 17-308. [14]

Issuance, contents of permit

Duty of Secretary to issue

(a) The Secretary shall issue a permit to any applicant who meets the requirements of this subtitle.

Contents

(b) The Secretary shall include on each permit that the Secretary issues:

(1) The name of the tissue bank;

(2) The name of its director;

(3) The name of its owner; and

(4) The classes of services that the tissue bank may offer.


Public Health Code – Definitions

“Tissue bank” means a person that is licensed, accredited, or regulated under federal or state law to engage in the recovery, screening, testing, processing, storage, or distribution of tissue.
26:6-71. Prohibition upon recovery and research activities without registration; terms of registration

a. No person shall engage in the recovery of a human body or part donated in this State for education, research, or the advancement of medical, dental, or mortuary science pursuant to P.L.1969, c. 161 (C.26:6-57 et seq.) or any subsequent statute adopted pursuant thereto, unless the person is registered as an anatomical research recovery organization with the Department of Health pursuant to this act.

The registration required pursuant to this act shall be in addition to any license or permit required by a local board of health, other local health agency, or any State or federal agency.

b. The registration shall be valid for a one-year period and may be renewed subject to compliance with the requirements of this act. The commissioner shall establish such registration and renewal fees as may be reasonable and necessary to carry out the purposes of this act.

c. The commissioner may enter and inspect the premises of any anatomical research recovery organization and the books and records as is reasonably necessary to carry out the provisions of this act.

N.J.S.A. 26:6-70 Definitions

"Anatomical research recovery organization" means a nonprofit corporation engaged in the recovery of a human body or part donated for education, research, or the advancement of medical, dental, or mortuary science pursuant to P.L.1969, c. 161 (C.26:6-57 et seq.) or any subsequent statute adopted pursuant thereto, where part or all of the recovery takes place in this State. Anatomical research recovery organization shall not include an accredited institution of higher education in this State that uses an anatomical gift for its own educational or research purposes and is not engaged in the distribution of a human body or part to another person or entity.

N.J.S.A. 26:6-25

26:6-25. Necessity of transit permit

No person shall ship or receive for shipment within this state or to any point outside the state, by any common carrier, a dead body until a transit permit has been issued by the local registrar of the district in which the death occurred.
state unless a license has been issued pursuant to this article.

2. An application for a license for a bank or storage facility shall contain the name of the operator, its officers, directors, principal stockholders, and controlling persons, a description of its organizational structure, the kind or kinds of procurement or storage services to be provided, the location and physical description of the bank or storage facility, and such other information as the department may require.

3. A license shall not be issued unless the department finds that the premises, equipment, personnel, rules and by-laws, and standards of service are fit and adequate and that the bank or storage facility will be operated in the manner required by this article.

4. Prior to approving an application for a license to operate a bank or storage facility which procures or stores tissue for transplantation or therapy purposes, the department shall consider:

   (a) the applicant's ability to arrange for the acquisition and preservation of usable donated tissue within a designated geographic area of service and to arrange for the transportation of such tissue when necessary;

   (b) the applicant's ability to obtain effective agreements for tissue procurement with hospitals;

   (c) the applicant's ability to conduct and participate in systematic efforts, including professional and public education, to procure usable tissue from potential donors;

   (d) the applicant's ability to establish and meet quality standards for the acquisition and storage of tissue;

   (e) the applicant's ability to arrange for the selection and testing of donors and donated tissue, including the performance of donor selection and required laboratory tests including typing and processing;

   (f) the character and competence of the operator, its officers, directors, principal stockholders and controlling persons, including the quality of care provided through any health care entities operated or controlled by such persons; and

   (g) with respect to banks and storage facilities created after the effective date of this paragraph, the existence and activities of other banks and storage facilities in the geographic area to be served by the applicant.

5. No hospital or other facility and no physician shall permit any person to procure tissue or non-transplant organs unless such person has been licensed in accordance with this article, or has been asked by a licensed bank or storage facility to procure a specified tissue or non-transplant organ. No bank or storage facility shall sell or otherwise transfer tissue for valuable consideration. Valuable consideration shall not include reasonable costs associated with the procurement, processing, storage and distribution of tissue. Nothing herein shall impair the provisions of section forty-three hundred seven of this chapter.

**NY PUB HEALTH § 4362**

1. No person shall own or operate an organ procurement organization that is principally located or operated in New York state unless: (a) the organization is currently designated by the secretary of health and human services as an organ procurement organization; and (b) the organ procurement organization is operated by a not-for-profit corporation having a board of directors which meets no less than four times annually or is operated by a hospital and has an advisory board which meets no less than four times annually. At least thirty percent of the members of the board of directors or advisory board shall be members of the public not otherwise directly or indirectly affiliated with a transplant center or organ procurement organization, and not more than fifty percent shall be surgeons or physicians. Such board of directors or advisory board shall include representatives of more than one transplant center. The board of directors of an organ procurement organization operated by a not-for-profit corporation or the advisory board of an organ procurement organization operated by a hospital shall be responsible for developing and adopting the written by-laws and policies that govern the operation of the organ procurement organization. All such by-laws and policies for an organ procurement organization operated by a hospital shall be subject to approval by the board of directors of the hospital. Written policies shall include, but not be limited to: (i) policies and procedures to educate the public and health care professionals about organ donations; (ii) medical standards for donor screening and testing; (iii) policies and procedures for the distribution of organs; (iv) procedures to ensure fiscal accountability of the organ procurement organization; and (v) policies concerning any arrangements or agreements that the organ procurement organization may enter with tissue banks storage facilities or other organ procurement organizations.

2. No hospital or other facility and no physician shall permit any person to, and no person shall, procure
organs for transplantation unless such person has been designated in accordance with this article or has been asked by a designated organ procurement organization to procure a specified organ.

3. The commissioner, in consultation with the transplant council, may promulgate regulations to establish standards for organ procurement organizations regarding organ sharing among organ procurement organizations in this state. Such standards shall include policies for sera sharing or other measures to meet the needs of patients who are highly sensitized and for whom it is difficult to identify a suitable kidney due to conditions such as a blood transfusion, immunization, prior pregnancy or a previous failed kidney transplant.

63 Okl.St.Ann. § 2209.1 [22]
§ 2209.1. Permits--Rules
A. On or after November 1, 1999, no person, corporation, partnership, association or other legal entity shall establish, operate or maintain a tissue bank that procures bone, skin, or connective tissue unless that entity has been issued a permit by the State Department of Health.

B. The State Board of Health shall promulgate rules necessary to implement the provisions of this section which shall include, but not be limited to:

1. Requirements for the tissue banks to submit an initial permit application that identifies the proposed service area, the tissue transplantation patient needs in the service area, the probable impact of the establishment and operation of the entity on other tissue banks currently servicing the area, and whether the tissue bank is a for profit or not for profit entity;

2. A requirement that tissue banks, within one (1) year after receipt of a permit, be accredited by the American Association of Tissue Banks or another nationally recognized accreditation organization for tissue agencies;

3. Provisions that all tissue banks employ a procurement technician or other technical operations personnel certified as a Certified Tissue Bank Specialist by the American Association of Tissue Banks or another nationally recognized accreditation or certification organization for tissue agencies and personnel;

4. A requirement that each tissue bank maintain compliance with federal Food and Drug Administration regulations;

5. A provision that each tissue bank have a medical director who is a physician licensed to practice medicine in this state;

6. Requirements for tissue banks to give priority in tissue distribution to the Oklahoma medical community and Oklahoma patients; and

7. A requirement that each tissue bank submit an annual report to the Department which shall provide the accreditation status of the entity, report of regulatory or internal inspections that affect quality, the certification status of personnel employed by the tissue agency, identity and qualification of the current medical director, type and geographic origins of donor tissue obtained, and units of processed tissue used for patients in the service area of the tissue bank.

C. A permit application or renewal thereof, shall be accompanied by a non-refundable fee established by the Board of Health not to exceed One Thousand Dollars ($1,000.00).

D. Upon receipt of a complete initial permit application, the Department shall cause a public notice of the proposed tissue bank to be published in a newspaper with the greatest circulation. The Department shall also provide written notice of the permit application to existing tissue banks in the state. Any person or organization may submit written comments regarding the proposed tissue bank to the Department.

E. The Department shall issue or deny an initial permit within seventy-five (75) days after publication of the notice. All permits shall be issued for a period not to exceed thirty-six (36) months and shall automatically expire unless renewed.
§ 109. Anatomical Donor Program Registration Act

A. This section shall be known and may be cited as the “Anatomical Donor Program Registration Act”.

B. The State Anatomical Board shall register all anatomical donor programs and non-transplant tissue banks in the state which meet the requirements of the Anatomical Donor Program Registration Act.

C. Before an anatomical donor program or a non-transplant tissue bank may receive whole body or partial body donations from any person or entity inside or outside the state, the anatomical donor program or non-transplant tissue bank shall register with the Board.

D. The Board shall specify the eligibility requirements for registration as an anatomical donor program or non-transplant tissue bank which, at a minimum, shall require such entities to be non-profit organizations.

E. The Board shall prescribe rules of conduct governing the practice of anatomical donor programs or non-transplant tissue banks registered pursuant to the Anatomical Donor Program Registration Act.

F. In order to address persons or entities which violate the provisions of the Anatomical Donor Program Registration Act or any rules promulgated thereto, the Board may:

1. Deny the issuance of a registration or suspend, revoke, or refuse to renew the registration of an anatomical donor program or non-transplant tissue bank, provided, however, that the Board may review, affirm, vacate, or modify a determination to deny, suspend, revoke, or refuse registration if the anatomical donor program or non-transplant tissue bank takes corrective actions;

2. Establish and administer administrative fines;

3. Initiate disciplinary or injunctive proceedings; and

4. Report alleged violations to the Attorney General or a district attorney as appropriate for further investigation or prosecution.

G. The Board shall report any violation it observes of the Oklahoma Uniform Anatomical Gift Act to the State Department of Health for further investigation and appropriate action.

H. The Board shall keep accurate and complete records of any proceedings initiated under the Anatomical Donor Program Registration Act.

I. The Board may issue a temporary registration to an anatomical donor program or non-transplant tissue bank which was previously registered but whose facilities were destroyed or damaged in order that, when appropriate safeguards are in place, the anatomical donor program or non-transplant tissue bank may continue to operate. During the effective period of the temporary registration, the Board may waive certain requirements if the anatomical donor program or non-transplant tissue bank is making a good faith effort to rebuild and restore its operations in order to meet all registration requirements.

J. The Board may maintain an office or secure facilities as deemed necessary by the Board in order to implement the Anatomical Donor Program Registration Act.
K. The Board shall promulgate rules as necessary to implement the provisions of the Anatomical Donor Program Registration Act.

O.R.S. § 441.082 [23]

441.082. Organ procurement organizations, tissue and eye banks; duty to register; penalties

(1) The Oregon Health Authority shall adopt by rule standards and a system of registration for every organ procurement organization, tissue bank and eye bank doing business in this state.

(2) An organ procurement organization, tissue bank or eye bank may not do business in this state unless it has registered with the authority.

(3) Each organ procurement organization, tissue bank and eye bank shall provide to the authority at least every three years current documentation of designation, certification and inspection as evidence of compliance with national standards and requirements under federal law.

(4) The authority may impose a civil penalty not to exceed $1,000 against an organ procurement organization, tissue bank or eye bank doing business in this state for failure to:

(a) Register with the authority;

(b) Report loss of designation, accreditation or certification within 60 days of the loss; or

(c) Supply the authority with requested current documentation of designation, certification and inspection.

(5) Civil penalties under this section shall be imposed in the manner provided under ORS 183.745.

O.R.S. § 441.079 [23]

441.079. Tissue banks; eye banks; registration; regulation

(1) As used in this section and ORS 441.082:

(a) “Entity” means an individual, corporation, business trust, partnership, limited liability company, association, joint venture or an instrumentality of an entity.

(b) “Eye bank” means an entity that is licensed or regulated under federal or state law to engage in the recovery, screening, testing, processing, storage or distribution of human eyes or parts of human eyes.

(c) “Health care facility” has the meaning given that term in ORS 442.015.

(d) “Organ procurement organization” means an entity designated by the United States Secretary of Health and Human Services as an organ procurement organization.

(e) “Tissue bank” means an entity that is licensed or regulated under federal or state law to engage in the recovery, screening, testing, processing, storage or distribution of tissue for transplants.

(2) Tissue banks and eye banks must be registered with and regulated by the United States Food and Drug Administration.

(3) A health care facility that performs organ transplants must:

(a) Be a member of the Organ Procurement and Transplantation Network established by the National Organ Transplant Act of 1984;

(b) Be regulated by the United States Department of Health and Human Services; and

(c) Use an organ procurement organization to obtain organs for transplants.

(4) A health care facility that performs tissue or corneal transplants must obtain the tissue or corneas from a tissue bank or an eye bank that is registered with and regulated by the United States Food and Drug Administration.

20 Pa.C.S.A. § 8617(f) [24]

Guidelines - Requests for anatomical gifts
| PA | (1) The Department of Health, in consultation with organ procurement organizations, tissue procurement providers and the Hospital Association of Pennsylvania, donor recipients and family appointed pursuant to section 8622(c)(3) (relating to The Governor Robert P. Casey Memorial Organ and Tissue Donation Awareness Trust Fund) shall, within six months of the effective date of this chapter, do all of the following:

   (i) Establish guidelines regarding efficient procedures facilitating the delivery of anatomical gift donations from receiving hospitals to procurement providers.

   (ii) Develop guidelines to assist hospitals in the selection and designation of tissue procurement providers.

(2) Each organ procurement organization and each tissue procurement provider operating within this Commonwealth shall, within six months of the effective date of this chapter, file with the Department of Health, for public review, its operating protocols. |

| SC | N/A. Organ and Tissue Procurement organizations “means the organ procurement organization designated to perform organ recovery services in South Carolina by the United States Department of Health and Human Services which also has the capability to procure tissue.” See Code 1976 § 44-43-910. |

| SD | N/A |

| TN | N/A |

| TX | N/A |

| UT | N/A |

| VA | **VA Code Ann. § 32.1-291.2** [29] **Definitions**

“Organ procurement organization” means a person designated by the Secretary of the United States Department of Health and Human Services as an organ procurement organization that is also a member of the Virginia Transplant Council.

... "Tissue bank" means a person that is licensed, accredited, or regulated under federal or state law to engage in the recovery, screening, testing, processing, storage, or distribution of tissue and that is a member of the Virginia Transplant Council, accredited by the American Association of Tissue Banks, and operating in the Commonwealth of Virginia.

Virginia Transplant Council is authorized “[t]o coordinate organ, tissue, and eye donation activities in the Commonwealth,” “[t]o advise the Board and Department of Health concerning organ, tissue, and eye donation activities, procurement, and transplantation efforts in Virginia[,]” and to establish bylaws as necessary. In Virginia, tissue banks must be members of the Virginia Transplant Council. See VA Code Ann. § § 32.1-297.1, 32.1-291.2. |

| WA | N/A |

| WI | **W.S.A. 157.06** [26] **Anatomical Gifts**

(24m) Authorization by coroner or medical examiner; tissue banks. |
3. A tissue bank under this paragraph is accredited by the American Association of Tissue Banks or audited at least once every 2 years by an organization that is accredited by the American Association of Tissue Banks.


[5] The Michigan State Licensing Section confirmed that Michigan does not license tissue banks specifically. They do license surgical outpatient facilities, but not tissue banks themselves.

[6] There is no applicable statutory requirement in South Carolina. In South Carolina, LifePoint, Inc. is the exclusive agency for receipt of referrals and donations. See Code 1976 § 44-43-970.

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