Article 43-B
Organ, Tissue and Body Parts

Section
4360. Definitions.
4361. Transplant council.
4362. Organ procurement organizations.
4363. Waiting lists for organs.
4364. Licensure of banks and storage facilities.
4365. Powers and duties of the commissioner.
4366. Enforcement.
4367. Separability.

S 4360 Definitions
The following words or phrases, used in this article, shall have the following meanings, unless the context otherwise requires:

1. "Bank" or "storage facility" means any person or facility, which procures, stores or arranges for the storage of (a) non-transplant organs, or (b) tissue for transplantation, therapy, education, research, or fertilization purposes, including autologous procedures. An organ procurement organization shall not constitute a bank or storage facility solely by virtue of storing or arranging for the storage of heart valves, nor shall any person or entity which stores non-transplant organs or tissues solely for the purpose of research and/or education conducted by such person or entity be deemed a bank or storage facility.

2. "Controlling person" means any person who by reason of a direct or indirect ownership interest (whether of record or beneficial) has the ability, acting either alone or in concert with others with ownership interests, to direct or cause the direction of the management or policies of said corporation, partnership, or other entity. Neither the commissioner nor any employee of the department nor any member of a local legislative body of a county or municipality, nor any county or municipal official, shall, by reason of his or her official position, be deemed a controlling person of any corporation, partnership, or other entity, nor shall any person who serves as an employee of any corporation, partnership, or other entity be deemed to be a controlling person of such corporation, partnership, or other entity as a result of such position or his or her official actions in such position.

3. "Non-transplant organ" means an organ procured for education or research purposes.

4. "Organ" means a human kidney, heart, heart valve, lung, pancreas, liver or any other organ designated by the commissioner in regulation in consultation with the transplant council.

5. "Organ procurement organization" or "procurement organization" means a person, facility, or institution engaged in procuring organs for transplantation or therapy purposes, but does not include (a) facilities or institutions which permit procurement activities to be conducted on their premises by employees or agents of an approved organ procurement organization, or (b) facilities or consortia of facilities which
conduct transplantation activities in accordance with article twenty-eight of this chapter when the organ is procured through an approved organ procurement organization, licensed bank or storage facility, or a living donor. A bank or storage facility shall not constitute an organ procurement organization solely by virtue of procuring heart valves.

6. "Person" means an individual, corporation, government or governmental subdivision or agency other than the office of mental health, business trust, estate trust, partnership or association, or any other legal entity.

7. "Principal stockholder" means any person who owns (whether of record or as beneficiary), holds or has the power to vote, ten percent or more of any class of securities issued by a corporation.

8. "Procure" or "procurement activity" means any activity which is necessary for the procurement of organs or tissue for transplantation, research, education, therapy, fertilization, or autologous purposes including solicitation, retrieval, donor selection and testing, clinical laboratory testing, including typing, preservation, transportation, allocation, distribution, storage, and payment activities.

9. "Service area" means the geographic area of service approved by the secretary of health and human services, or, in the absence of such approval, by the department.

10. "Tissue" means a human eye, skin, bone, bone marrow, heart valve, spermatozoon, ova, artery, vein, tendon, ligament, pituitary gland or a fluid other than blood or a blood derivative.

**S 4361 Transplant council**

1. There shall be created in the department a transplant council which shall advise the commissioner on matters relating to organ procurement organizations, banks, and storage facilities and other issues related to the procurement, storage, allocation, distribution, and transplantation of organs and tissue. The council shall consist of twenty-one members of which seven, including the chairperson, shall be appointed by the governor, seven by the temporary president of the senate and seven by the speaker of the assembly. The transplant council shall be composed of members of the general public, transplant recipients or donors or their family members, representatives of organ procurement organizations and banks or storage facilities, physicians with expertise in organ and tissue transplantation and the care of persons with end stage disease resulting from organ failure and persons with expertise in histocompatibility typing, law and ethics.

2. The terms of office of members of the transplant council shall be three years, provided, however, that of the members first appointed seven shall be appointed for terms which shall expire on December thirty-first, nineteen hundred ninety-two, seven shall be appointed for terms which shall expire on December thirty-first, nineteen hundred ninety-four and seven shall be appointed for terms which shall expire December thirty-first, nineteen hundred ninety-six. Vacancies shall be filled by appointment in like manner for the unexpired term of such member.

3. The transplant council shall meet as frequently as its business may require, and at least twice in each year.
4. The transplant council shall enact and from time to time may amend by-laws in relation to its meetings and the transaction of its business.
5. The members of the council shall receive no compensation for their services as members of the council, but each of them shall be allowed the necessary and actual expenses which are incurred in the performance of his or her duties under this article.
6. (a) The transplant council shall review existing federal law and policies, including federal regulations and the policies of the federal organ procurement and transplantation network governing organ procurement organizations and procurement activities, and make recommendations to the commissioner regarding state regulation of organ procurement organizations and activities and tissue banks and tissue procurement activities provided that the council shall make initial recommendations to the commissioner on or before April first, nineteen hundred ninety-two.
   (b) Prior to the commissioner's final approval and promulgation of such proposed rules and regulations, if such rules and regulations are modified in any respect, they shall be submitted to the council in accordance with the provisions of subdivision three of section forty-three hundred sixty-five of this article. If the commissioner determines not to promulgate such proposed rules and regulations, the commissioner shall provide a written explanation of such determination to the council.

S 4362 Organ procurement organizations
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.

S 4363 Waiting lists for organs

1. All organs retrieved for transplantation in New York state shall be allocated according to waiting lists developed by the organ procurement organization in the service area in which the organ is procured, provided, however, that nothing herein shall preclude the exercise of medical judgment in determining the suitability of a proposed recipient to receive a particular organ, and provided further, however, that if an organ is brought into a service area of an organ procurement organization from the service area of another organ procurement organization, the organ shall be allocated according to the waiting list developed by the organ procurement organization in the service area in which the organ is to be implanted. Nothing in this section shall prohibit:
   (a) an individual donor from designating the recipient of an organ;
   (b) organ sharing with other organ procurement organizations in accordance with federal and state standards including standards 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;
   (c) organ sharing with other organ procurement organizations in accordance with organ sharing agreements approved by the commissioner.

2. No organ procurement organization designated to serve any part of New York state shall place any person on a waiting list for the allocation of organs for transplantation if that person is listed on any other waiting list for the allocation of that organ maintained by any other organ procurement organization designated to serve any part of New York state.
3. No person may place his or her name on a waiting list for the allocation of organs for transplantation maintained by an organ procurement organization designated to serve any part of New York state if the person is listed on any other waiting list for the allocation of that organ maintained by any other organ procurement organization designated to serve any part of New York state. Each facility performing transplant services shall inform a patient of the prohibition against being placed on multiple waiting lists before arranging for the placement of the patient on a waiting list.

4. In policies and procedures for distributing organs, no organ procurement organization shall consider or give any preference to patients in a facility based upon the facility's past or present procurement performance or its past or present relationship with a donor hospital.

S 4364 Licensure of banks and storage facilities

1. No person shall own or operate a bank or storage facility that conducts procurement activity in New York 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.

S 4365 Powers and duties of the commissioner
1. The commissioner, in consultation with the transplant council, may promulgate
regulations to establish standards for banks and storage facilities other than those
owned or operated by the office of mental health. Such standards may provide for
the following: the organizational structure of banks and storage facilities; the
geographic scope of licensed banks and storage facilities; donor selection and
solicitation practices; tissue and non-transplant organ retrieval practices;
transportation practices; required clinical laboratory tests for suitable donors,
recipients and tissue; histocompatibility standards; allocation criteria; reporting
requirements; record keeping requirements; accounting procedures; staff
requirements; the content of agreements with hospitals from which tissues and non-
transplant organs will be procured; and the content of agreements with organ
procurement organizations, educational institutions, other banks and storage
facilities, and other entities providing services to banks or storage facilities in
connection with the procurement, storage, and distribution of tissue and non-
transplant organs. The commissioner and the commissioner of mental health shall
enter into a cooperative agreement to establish standards for banks and storage
facilities owned or operated by the office of mental health which may include
standards for donor selection and solicitation practices; tissue and non-transplant
organ retrieval practices; transportation practices; reporting requirements; record
keeping requirements; the content of agreements with hospitals from which tissues
and non-transplant organs will be procured, and the content of agreements with
other banks and storage facilities.
2. Notwithstanding any inconsistent provision of article five of this chapter, the
commissioner, in consultation with the transplant council, may promulgate
regulations to establish quality control standards governing tissue typing conducted
by or at the request of organ procurement organizations and facilities performing
transplant services. Such regulations may eliminate duplicative testing by
laboratories by limiting within a service area the performance of histocompatibility
matching and tissue typing services for cadaveric organ donations for
transplantation in New York state.
3. At least sixty days prior to the commissioner's final approval of rules and
regulations proposed pursuant to this article, other than emergency rules and
regulations, the commissioner shall submit such proposed rules and regulations to the council for its review. The council shall review such rules and regulations and submit its recommendations to the commissioner within sixty days. The commissioner shall not act in a manner inconsistent with the recommendations of the council without first providing to the council a written explanation of the reasons therefor.

4. The commissioner may inquire into the operation of banks and storage facilities and may conduct periodic inspections of banks and storage facilities including methods, procedures, materials, staff and equipment.

5. Organ procurement organizations, banks, storage facilities, and other persons engaged in procurement activities shall submit, in a form prescribed by the department, periodic reports of procurement, storage and distribution activities and such other information as the commissioner may require to carry out the provisions of this article. Where available, the commissioner shall utilize information reported by organ procurement organizations to the organ procurement and transplantation network established pursuant to section three hundred seventy-two of the federal public health services act.

6. In consultation with the transplant council, the commissioner is authorized to establish subcategories of licenses based upon the tissue and non-transplant organs to be procured or stored by banks and storage facilities and the activities to be conducted and may include different standards for each subcategory of license.

7. Nothing contained within this article shall limit the authority of the council on human blood and transfusion services to adopt rules and regulations concerning blood and bone marrow in accordance with article thirty-one of this chapter.

**S 4366 Enforcement**

1. The commissioner may revoke, suspend, limit or annul, a bank or storage facility license or may fine the holder thereof on proof that the license holder or one or more persons in its employ:
   
   (a) has engaged in misrepresentation in obtaining the license or in the operation of the bank or storage facility;
   
   (b) has engaged or attempted to engage in or represented itself as being entitled to perform any procurement or storage activity not authorized in the license;
   
   (c) has demonstrated incompetence or has shown recurrent errors in the performance of procurement or storage activities;
   
   (d) has been convicted of a felony.

2. No license shall be revoked, suspended, limited, or annulled or fine imposed without an opportunity for a hearing; provided, however, that a license may be temporarily suspended without a hearing for a period not in excess of sixty days upon notice to the license holder following a finding by the commissioner or his designee that the public health, safety, or welfare is in imminent danger.

   (a) the commissioner or his designee shall fix a time and place for the hearing;
   
   (b) a copy of the charges, together with a notice of the time and place of the hearing, shall be mailed to the license holder at the address of the bank or storage facility;
(c) all orders or determinations hereunder shall be subject to review as provided in article seventy-eight of the civil practice law and rules.

3. The supreme court may enjoin violations or threatened violations of any provisions of this article or of the rules and regulations issued thereunder. Upon request of the commissioner, the attorney general shall maintain an action in the supreme court in the name of the people of the state to enjoin any such violation.

S 4367 Separability
If any clause, sentence, paragraph, section or part of this article shall be adjudged by any court of competent jurisdiction to be invalid, the judgment shall not affect, impair, or invalidate the remainder thereof, but shall be confined in its operation to the clause, sentence, paragraph, section, or part thereof directly involved in the controversy in which the judgment shall have been rendered.