

**DISTRICT OF  
COLUMBIA  
MUNICIPAL  
REGULATIONS**

**TISSUE BANKS**

**CHAPTER 3. TISSUE BANKS**

Secs.

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**300. GENERAL PROVISIONS**

- 300.1 This chapter shall provide minimum standards for the establishment, maintenance, and operation of tissue banks; and shall carry out the stated purposes of the D.C. Tissue Bank Act, as well as to meet the requirements of § 4(b) of the Act.
- 300.2 The provisions of this chapter shall apply to the establishment, maintenance, and operation of tissue banks.
- 300.3 In the absence of specific requirements in the Act and in this chapter, the management and operation of any tissue bank shall be in accordance with good medical and public health practice.
- 300.4 Each section and every part of each section of this chapter shall be independent of every other section or part of a section, and the finding or holding of any section or part of a section shall be void or ineffective for any cause shall not be deemed to affect any other section or part.

**301. LICENSES**

- 301.1 No person shall operate or hold himself or herself out as operating a tissue bank in the District after May 25, 1963, without being licensed, or designated by the licensee, as required by the Act and this chapter, unless the tissue bank is operated by, or in connection with, a federal or District agency.
- 301.2 Application for a license to operate a tissue bank shall be made to the Director on forms furnished by the Director for that purpose. Each application shall contain whatever other information concerning the operation of the bank as the Director may require, including but not limited to a statement of the general purposes and scope of the bank.

- 301.3 Each application for a license to operate a tissue bank shall be accompanied by payment of a fee of twenty-five dollars (\$ 25).
- 301.4 Each application for a license to operate a tissue bank shall be signed and certified correct by the operator, unless the application is made by a person or persons licensed to operate a hospital, in which case it shall be signed and certified by the person licensed to operate the hospital.
- 301.5 Each tissue bank license shall specify the following information:
- (a) The name of the licensee;
  - (b) The location of the bank; and
  - (c) The date the license will expire.
- 301.6 In any case in which a tissue bank is sponsored by and obtains a substantial portion of its financial support from a non-profit, charitable organization exempted from taxation under the provisions of [§ 501 of the Internal Revenue Code of 1954](#), as amended, the name of the organization may, at the request of the applicant, be shown on the tissue bank license along with the name of the licensee.
- 301.7 Notwithstanding the provisions of § 301.1 of this section, the non-profit, charitable organization that substantially supports a tissue bank may indicate or advertise its sponsorship of the bank, using any style of name as the organization may elect.
- 301.8 Nothing in this section shall be construed as relieving the licensee from complying fully with all of the requirements of the Act and with this chapter.
- 301.9 Each tissue bank license shall be valid only for the licensee and the premises named in the license and only for the calendar year for which the license is issued.
- 301.10 The licensee shall frame the tissue bank license under clear glass or plastic, and post it in a conspicuous place on the licensed premises.
- 301.11 Whenever the Director finds that an applicant for a license does not meet the requirements of the Act or the provisions of this chapter, or that a licensee fails to comply with the Act or this chapter, the Director shall give written notice of the deficiency or failure to the applicant or licensee and shall require the applicant or licensee to show cause why a license should be issued or why his or her license should not be suspended or revoked.
- 301.12 Whenever the Director determines that the applicant does not meet the requirements of the Act or this chapter, or that a licensee fails to comply with the Act or this chapter, or that it would be in the best

interests of the public health to deny, suspend, or revoke a license, the Director shall give written notice of that determination to the applicant or licensee by certified mail or personal service.

301.13 Any applicant or licensee may, within ten (10) days after receiving a notice as provided in § 301.12, request a hearing before the Director.

301.14 Not less than fifteen (15) days after receiving a request for a hearing, the Director shall fix a date and time for the hearing.

301.15 Any applicant for a license who is adversely affected by a determination made under the authority of this chapter may file an appeal in writing to the Board of Appeals and Review.

301.16 The appeal to the Board of Appeals and Review shall state the error alleged to be contained in any determination or refusal adversely affecting the applicant for a license or a licensee, and shall be filed within ten (10) days after receipt of the Director's determination.

## **302. OPERATION OF TISSUE BANKS**

302.1 Each tissue bank shall be directed by an operator who shall be a physician with authority and responsibility for the direction of the bank.

302.2 The tissue bank operator shall maintain a roster of all persons authorized by him or her to have access to the bank, and shall establish specific rules for the operation of the bank and for governing the conduct of persons permitted access to the bank.

302.3 The roster and rules required in § 302.2 shall be made available to the Director upon request.

302.4 Whenever the licensee is a person licensed to operate a hospital, the licensee shall designate a physician who shall be the operator of the tissue bank.

302.5 In the case of any tissue bank exempted from licensing under the provisions of § 4(e) of the Act, the individual directly in charge of the institution in which or in connection with which the tissue bank is operated shall designate a physician who shall be the operator of the bank.

302.6 The licensee shall notify the Director of any change of operator.

302.7 In the case of a tissue bank not required to be licensed under § 4(e) of the Act, the individual directly in charge of the institution in which or in connection with which the tissue bank is operated shall notify the Director of any change in the operator of the bank.

**303. RECORDS OF ACQUISITION AND WITHDRAWAL**

- 303.1 No tissue may be placed in any tissue bank unless a proper record is made of its acquisition on a form that has been approved by the Director.
- 303.2 The record required in § 303.1 shall consist of, but not be limited to, the following information:
- (a) Name of donor;
  - (b) Place of death;
  - (c) Date of death;
  - (d) Cause of death;
  - (e) Restrictions on the use of the tissue, if any, made by the donor or by the person having the right to the body;
  - (f) A complete description of the tissue, including categories of tissue and quantity of each category; and
  - (g) The signature of the physician who removed the tissue from the body of the deceased, and the signature of the operator.
- 303.3 No tissue may be placed in any tissue bank which has been acquired from another tissue bank, without being accompanied by a copy of the original record of acquisition and a detailed listing of the quantity and category of tissue.
- 303.4 No tissue may be withdrawn from a tissue bank unless a record of the withdrawal is made on a form approved by the Director.
- 303.5 The record of withdrawal required in § 303.4 shall include, but not be limited to, the following information:
- (a) A completed description of the tissue withdrawn, including categories of tissue and quantities of each category sent; and
  - (b) The purpose of withdrawal, that is, whether the tissue is to be used for human transplantation or for medico-surgical research.
- 303.6 Tissue shall be issued only to persons or institutions deemed qualified by the operator to use the tissue for the purposes set forth in the Act.
- 303.7 Whenever it becomes necessary to withdraw tissue from a tissue bank for any other purpose than for human transplantation or for medico-surgical research, a complete record of the withdrawal shall be made

on a form approved by the Director.

- 303.8 The record of withdrawal required in § 303.7 shall contain a complete description of the tissue withdrawn, the reasons for withdrawal, and the disposition made of the tissue.

#### **304. PHYSICAL AND SANITARY REQUIREMENTS**

- 304.1 The tissue bank operator shall at all times maintain sanitary conditions and sterile precautions appropriate to the procurement, banking, and issue of tissues, which, in the judgment of the Director, are consistent with accepted medical practices.
- 304.2 The location of the tissue bank shall be one that, in the judgment of the Director, will permit maintenance of the standard conditions and sterile precautions required in § 304.1.
- 304.3 The facilities and other equipment provided for use by the bank shall be adequate for the purposes and scope of the bank as indicated in the application for license, and as approved by the Director.

#### **305. INSPECTION**

- 305.1 The Director shall make inspections of tissue banks and their records as may be required in the enforcement of the Act and this chapter.
- 305.2 The tissue bank operator shall cooperate in any inspection to the extent of providing the Director with the necessary assistance to make an inspection.

#### **306. TRANSPORTATION OF TISSUE**

- 306.1 Tissue may be transported to or from a tissue bank for any of the purposes of the Act or this chapter when accompanied by a signed copy of the applicable record required by § 303 of this chapter.

#### **399. DEFINITIONS**

- 399.1 The definitions contained in the Act are incorporated by reference in this chapter and made a part of this chapter.
- 399.2 In addition to the definitions contained in the Act, the terms in this chapter shall have the meanings ascribed to them in this section:

Act - the District of Columbia Tissue Bank Act (Public Law 87-656; 76 Stat. 534; [D.C. Code, §§ 2-1601 through 2-1607](#)).

Department - the Department of Human Services of the District of Columbia.

Director - the Director of Human Services of the District of Columbia, or the Director's duly designated representative.

District - the territorial area known as the District of Columbia or the municipal government of the District of Columbia, as the context requires.

Operator - the licensee if the licensee is not a hospital; the physician designated by the licensee if the licensee is a hospital; or the physician designated to operate any tissue bank which, under the provisions of § 4(e) of the Act, is not required to be licensed.