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Title 10
MARYLAND DEPARTMENT OF HEALTH

Subtitle 50 TISSUE BANKS

10.50.01 Tissue Banks

Authority: Health General Article, §§17-302, [17-304,] 17-303, 17-305, 17-307, **[**17-310,**]** 17-313, Annotated Code of Maryland

Notice of Proposed Action

[25-130-P-I]

The Acting Secretary of Health proposes to amend Regulations **.03**, **.04**, **.07**, **.10**, and **.11**, repeal existing Regulations **.05**, **.06**, and **.09**, recodify existing Regulation **.08** to be Regulation **.09**, and adopt new Regulations **.06** and **.08** under **COMAR 10.50.01 Tissue Banks**.

Statement of Purpose

The purpose of this action is to set minimum, reasonable standards for permitting of Tissue Banks in Maryland.

This chapter is intended to maximize safety and quality of Tissue Bank operations and tissue components received by Marylanders, while updating and establishing reasonable standards for the growing industry.

The updated regulations will:

(1) Reflect current Maryland law;

(2) Delete obsolete terminology;

(3) Address concerns brought forth by the industry; and

(4) Reflect current quality and safety standards of medical laboratories.

Estimate of Economic Impact

The proposed action has no economic impact.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Jordan Fisher Blotter, Director, Office of Regulation and Policy Coordination, Maryland Department of Health, 201 West Preston Street, Room 534 Baltimore, Maryland 21201, or call 410-767-0938, or email to mdh.regs@maryland.gov. Comments will be accepted through July 28, 2025. A public hearing has not been scheduled.

Editor's Note on Incorporation by Reference

Pursuant to State Government Article, §7-207, Annotated Code of Maryland, Standards for Tissue Banking (American Association of Tissue Banks, 14th Edition), Sections C, D, E, F, G, H, J, K, L, and M1-8 only; Standards for Blood Banks and

Transfusion Services (Association for the Advancement of Blood & Biotherapies), 34th Edition; and International Quality Plasma Program (IQPP) (Plasma Protein Therapeutics Association): (a) Community-based Donor Standard V5 (2020); (b) Cross Donation Management Standard V3 (2014); (c) Recording Donor Adverse Events V2 (2018); (d) Donor Education Standard V3 (2014); (e) Donor Fluid Administration Standard V1 (2014); (f) Use of National Donor Deferral Registry Standard V3 (2008); (g) Qualified Donor Standard V5 (2020); (h) Viral Marker Standard V5 (2022); (i) Personnel Education and Training Standard V5 (2019); (j) Plasma Collection Facility Standard V4 (2019); (k) Quality Assurance Standard V5 (2020) have been declared documents generally available to the public and appropriate for incorporation by reference. For this reason, they will not be printed in the Maryland Register or the Code of Maryland Regulations (COMAR). Copies of these documents are filed in special public depositories located throughout the State. A list of these depositories was published in 52:2 Md. R. 53 (January 24, 2025), and is available online at www.dsd.maryland.gov. These documents may also be inspected at the office of the Division of State Documents, 16 Francis Street, Annapolis, Maryland 21401.

.03 Definitions.

A. (text unchanged)

B. Terms Defined.

(1)—(3) (text unchanged)

(4) "Approval of the removal plan" means that the OHCQ has determined that the tissue bank's removal plan, if implemented appropriately, will remove the likelihood that serious harm will occur, or recur.

[(4)**]** *(5)*—**[**(6)**]** *(7)* (text unchanged)

(8) "Designated qualified employee" means an employee who has been delegated one or more responsibilities by the technical director or medical director and who possesses the training and experience to perform the delegated responsibility.

[(7)**]** *(9)*—**[**(11)**]** *(13)* (text unchanged)

(14) "Immediate corrective action" means all actions the tissue bank has taken or will take to immediately address the noncompliance that resulted in or made serious harm or death likely.

(15) "Immediate jeopardy" means a situation in which immediate corrective action is necessary because the tissue bank's noncompliance with one or more licensure requirements has already caused, is causing, or is likely to cause, at any time, serious harm or death, to individuals served by the tissue bank or to the health or safety of the general public.

(16)"Informal dispute resolution (IDR)" means an informal process that provides a tissue bank the opportunity to dispute one or more deficiencies cited in a written statement of deficiencies issued by the Department or the Department's designee related to a recent survey.

[(12)**]** *(17)* (text unchanged)

[(13)**]** *(18)* Leukocyte-**[**poor**]** *Poor* Tissue.

(a) "Leukocyte- **[**poor**]***Poor* tissue" means tissue that does not contain a significant or substantial number of potentially viable leukocytes.

(b) "Leukocyte-**[**poor**]***Poor* tissue" includes but is not limited to:

(i)—(vii) (text unchanged)

[(14)**]** *(19)* Leukocyte-**[**rich**]***Rich* Tissue.

(a) "Leukocyte-**[**rich**]***Rich* tissue" means tissue that may contain a significant or substantial number of potentially viable leukocytes.

(b) "Leukocyte-**[**rich**]** *Rich* tissue" includes but is not limited to:

(i)—(vi) (text unchanged)

[(15)**]** *(20)* "Medical director" means a physician who:

(a) (text unchanged)

(b) Is responsible for all medical aspects of the tissue bank's **[**services**]** *operations, unless the technical director meets the qualifications stated in Regulation .10B of this chapter*.

[(16)**]** *(21)*—**[**(17)**]** *(22)* (text unchanged)

(23) "Need for immediate corrective action" means immediate corrective action is necessary to remove the jeopardy.

(24) "Noncompliance" means the tissue bank is not compliant with one or more licensure requirements.

[(18)**]** *(25)*—**[**(19)**]** *(26)* (text unchanged)

[(20)**]** *(27)* Permit.

(a) (text unchanged)

(b) "Permit" includes a provisional permit, except as otherwise indicated in Regulation .06 of this chapter.

(28) "Plan of correction" means a written plan submitted by the tissue bank to the OHCQ which documents steps the tissue bank will take to come into compliance with the licensure requirements.

[(21)**]** *(29)*—**[**(22)**]** *(30)* (text unchanged)

(31) "Removal plan" means the tissue bank's written plan that documents:

(a) The immediate corrective action a tissue bank will take to prevent serious harm from occurring or recurring;

(b) All actions to remove past, present, and future jeopardy; and

(c) The date by which the entity asserts the likelihood for serious harm to any recipient no longer exists.

[(23)**]** *(32)*—**[**(26)**]** *(35)* (text unchanged)

(36) "Serious harm" means the situation has already caused, is causing, or is likely to cause, at any time, serious injury, serious impairment, or death, to individuals served by the tissue bank or to the health or safety of the general public.

[(27)**]** *(37)* (text unchanged)

(38) "Statement of Deficiencies" means the written notification that the OHCQ issues to the provider that contains a listing of deficiencies cited that require correction.

[(28)**]** *(39)* "Technical director" means an individual who:

(a) (text unchanged)

(b) **[**Is responsible for supervising the technical, scientific, and administrative operations of a tissue bank**]** *Will oversee and be responsible for all technical aspects of the tissue bank's operations*.

[(29)**]** *(40)* (text unchanged)

[(30)**]** *(41)* Tissue Bank.

(a) "Tissue bank" *means an establishment that obtains, stores, processes, distributes, or sells human blood or other human tissue for use in the human body.*

(b) "Tissue bank" includes a person or facility that provides or engages in one or more services involving tissue from living or cadaveric donors for:

(i)—(iv) (text unchanged)

[(b)**]** *(c)* (text unchanged)

[(31)**]** *(42)* (text unchanged)

.04 Incorporation by Reference.

A. (text unchanged)

B. Documents Incorporated.

(1) Standards for Tissue Banking (American Association of Tissue Banks, **[**13th**]** *14th* Edition), Sections C, D, E, F, G, H, J, K, L, and M1-8 only;

(2) Standards for Blood Banks and Transfusion Services **[**(American Association of Blood Banks, 29th Edition);**]** *(Association for the Advancement of Blood & Biotherapies), 34th Edition*;

(3) International Quality Plasma Program (IQPP) (Plasma Protein Therapeutics Association):

(a) Community-based Donor Standard V5 (2020);

(b) Cross Donation Management Standard V3 (2014);

(c) Recording Donor Adverse Events V2 (2018);

(d) Donor Education Standard V3 (2014);

(e) Donor Fluid Administration Standard V1 (2014);

(f) Use of National Donor Deferral Registry Standard V3 (2008);

(g) Qualified Donor Standard V5 (2020);

(h) Viral Marker Standard V5 (2022);

(i) Personnel Education and Training Standard V5 (2019);

(j) Plasma Collection Facility Standard V4 (2019);

(k) Quality Assurance Standard V5 (2020); and

[(3)**]** *(4)*—**[**(5)**]** *(6)* (text unchanged)

.06 Permitting Procedure.

A. Application. An application is not complete until the OHCQ has received the completed permit application and all required documents.

B. Initial Inspection. The OHCQ shall inspect or have an inspection conducted by an accreditation organization for each tissue bank when an initial Maryland permit to operate is sought.

C. Issuance of a Permit. The Secretary shall issue a permit to an applicant who meets the requirements of this chapter to:

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

(2) Represent for service in the State a tissue bank that is inside the State or outside the State.

D. Issuance of a Permit and Provisional Permit.

(1) Permit and Provisional Permit Content. A permit and provisional permit shall state:

(a) The name of the tissue bank;

(b) The name of the tissue bank's medical director;

(c) The name of the tissue bank's owner or owners; and

(d) The class or classes of the tissue bank.

(2) Provisional Permit.

(a) The Secretary may issue a provisional permit before or after an initial inspection.

(b) A provisional permit:

(i) Is valid for 180 calendar days or a lesser period as determined by the Secretary;

(ii) May not be renewed; and

(iii) Shall automatically expire without notice upon the sooner of the date set for its expiration or upon issuance of a permit.

E. Permit Requirement. 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 a tissue bank that is:

(a) In this State; or

(b) Outside this State.

F. Operating Without a Permit.

(1) Unless a person has a permit issued by the Secretary to operate, represent, or service a tissue bank in this State, a person may not:

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

(b) Represent or service in this State a tissue bank that is in this State or outside this State.

(2) A permit holder may not operate, represent, or service a tissue bank class other than that authorized in the permit.

G. Cessation of Operations. If a tissue bank ceases operation for 180 calendar days, then:

(1) The OHCQ will void the permit to operate a tissue bank in the State; and

(2) The tissue bank shall return the permit to the OHCQ.

H. Permit Application Administratively Closed.

(1) After 180 calendar days from the date of initial receipt, the OHCQ may deem an incomplete permit application inactive and administratively close the application.

(2) An applicant whose application is administratively closed may reapply for a permit by submitting a new application.

I. Change of Medical Director, Name, or Location of a Tissue Bank. A tissue bank undergoing a change in medical director, name, or location shall:

(1) Notify the OHCQ 10 calendar days before a change occurs; and

(2) Apply to the OHCQ for an amended permit or provisional permit within 30 calendar days after a change takes place.

J. Nontransferability. A permit or provisional permit may not be transferred from one owner of a tissue bank to another.

K. Denial, Suspension, Revocation — Causes. The Secretary may deny, suspend, or revoke a permit or provisional permit if the tissue bank or the tissue bank's technical director, medical director, or both fail to meet requirements of this chapter, including, but not limited to:

(1) Failure within a specified time to correct a cited deficiency identified during an inspection;

(2) Repetitive or consistent errors;

(3) Deliberate falsehood; or

(4) Failure to apply for an amended permit or provisional permit within 30 calendar days after a tissue bank undergoes a change in tissue bank class, medical director, name, or location.

L. Denial, Suspension, and Revocation — Hearing Requirement.

(1) When the Secretary denies an application for a permit, the Secretary shall inform the permit applicant in writing:

(a) Of the date the denial takes effect;

(b) Of the reason for the denial; and

(c) That the permit applicant has an opportunity for a hearing on the matter in accordance with State Government Article, §10-226, Annotated Code of Maryland.

(2) Unless the Secretary finds that a danger to public health, safety, or welfare summarily requires that emergency action be taken to correct a deficiency, the Secretary shall inform the permit holder or provisional permit holder, in writing:

(a) Of the date a suspension or revocation of the permit or provisional permit takes effect;

(b) Of the reason for the suspension or revocation; and

(c) That the permit holder or provisional permit holder has an opportunity for a hearing on the matter before the suspension or revocation takes effect, in accordance with State Government Article, §10-226, Annotated Code of Maryland.

(3) When a finding is made that the public health, safety, or welfare summarily requires that emergency or immediate corrective action be taken, the Secretary shall inform the permit holder or provisional permit holder in writing:

(a) Of the date a suspension or revocation of the permit or provisional permit takes effect;

(b) Of the reason for the suspension or revocation; and

(c) That the permit holder or provisional permit holder has an opportunity for a hearing on the matter, after the suspension or revocation takes effect, in accordance with State Government Article, §10-226, Annotated Code of Maryland.

(4) Reapplication After Revocation. A tissue bank that has had its permit or provisional permit revoked may apply for a new permit 30 calendar days after revocation and upon presentation to the Secretary of evidence of capability and intention to comply with the standards and requirements of this chapter.

M. Return of Permit. If a tissue bank's permit is amended, suspended, or revoked, the original permit is void and the tissue bank's technical director shall return the permit to the OHCQ.

.07 Accredited Tissue Bank and Accrediting Organization.

A. (text unchanged)

B. Accredited Tissue Bank — Requirements. In addition to meeting the requirements for accreditation, as set forth by a tissue bank's accrediting organization, an accredited tissue bank shall:

(1) (text unchanged)

(2) Be subject to inspection by the OHCQ to:

(a)—(b) (text unchanged)

(c) Determine whether a **[**permittee**]** *permit holder* is operating a tissue bank beyond the scope of the permit; **[**and**]**

(d) Validate findings of a tissue bank's accrediting organization**[**.**]***; and*

(e) Verify compliance with licensure requirements.

C. (text unchanged)

D. Change in Accreditation Status. Tissue banks shall report all changes in accreditation status to the OHCQ within seven calendar days of becoming aware of the change.

.08 Inspection by OHCQ.

A. Open for Inspection. A permit holder shall allow an on-site inspection by the OHCQ, or any designee by OHCQ, at any time during the tissue bank's regular hours of operation, to evaluate the tissue bank's compliance with the applicable requirements, conditions, and standards of this chapter.

B. Content of Inspection. An inspection may include, but is not limited to, observation and examination of:

(1) Tissue bank facilities and physical security;

(2) Equipment;

(3) Quality assurance and quality control policies and records;

(4) Operating procedures, policies, and records;

(5) Personnel and personnel records;

(6) Donor documentation and records; and

(7) Other records and files pertinent to this chapter.

C. Access to Records. Tissue bank employees shall make data and records accessible within a reasonable time during an inspection by OHCQ or any designee by OHCQ.

D. Permitted Tissue Bank. A permit holder operating a tissue bank under a provisional permit or a permit shall be subject to:

(1) An initial inspection conducted by the OHCQ;

(2) Periodic inspections by the OHCQ; and

(3) Other inspections by the OHCQ to determine if the tissue bank is in compliance with licensure requirements.

E. Accredited Tissue Bank. An accredited tissue bank is subject to:

(1) An initial inspection by an accreditation organization or the OHCQ;

(2) Periodic inspections by an accreditation organization or the OHCQ; and

(3) Other inspections by the OHCQ to determine if the tissue bank is in compliance with licensure requirements.

F. Notice of Deficiencies. If a survey identifies noncompliance with a requirement, the Department shall:

(1) Issue a written Statement of Deficiencies that cites each deficiency;

(2) Require the tissue bank to submit an acceptable plan of correction within 10 calendar days of receipt of the Statement of Deficiencies;

(3) Notify the tissue bank of any sanctions imposed or that failure to correct the violation may result in sanctions; and

(4) Offer the tissue bank the opportunity for informal dispute resolution (IDR).

G. Plan of Correction.

(1) The tissue bank shall submit a written plan of correction to the OHCQ in response to a Statement of Deficiencies documenting the steps the permit holder will take to come into compliance, including:

(a) How the tissue bank will correct each deficiency;

(b) The date by which each deficient practice will be corrected;

(c) How the tissue bank will prevent the deficient practice from recurring; and

(d) Who will be responsible for ensuring the deficiency will not reoccur.

(2) Failure of the tissue bank to return an acceptable plan of correction within 10 calendar days after receipt of a Statement of Deficiencies may result in a sanction.

(3) A tissue bank's request for an IDR does not change the tissue bank's requirement to submit a plan of correction for all deficiencies within 10 calendar days after receipt of the Statement of Deficiencies.

(4) If an immediate jeopardy is identified during a survey, the tissue bank's plan of correction shall completely correct all noncompliance associated with the immediate jeopardy.

H. Immediate Jeopardy.

(1) Declaration of Immediate Jeopardy.

(a) When the Department identifies a situation in which immediate corrective action is necessary because the tissue bank's noncompliance with one or more licensure requirements has already caused, is causing, or is likely to cause, at any time, serious harm or death, to individuals served by the tissue bank or to the health or safety of the general public, an immediate jeopardy will be declared.

(b) The Department shall provide the tissue bank a written notice that includes a description of the situation that constitutes an immediate jeopardy.

(2) Removal Plan. The tissue bank shall submit a written removal plan to the Department that includes:

(a) The immediate corrective action a tissue bank will take to prevent serious harm from occurring or recurring;

(b) All actions to remove past, present, and future jeopardy; and

(c) The date by which the entity asserts the likelihood for serious harm to any recipient or the general public will no longer exist.

(3) The Department's Review of the Removal Plan.

(a) The OHCQ staff shall review the tissue bank's removal plan to determine if the removal plan, if implemented appropriately, will remove the likelihood that serious harm will occur, or recur.

(b) The OHCQ shall verify that the tissue bank has implemented the removal plan.

(4) The Department's Approval of the Removal Plan. The Department shall approve the removal plan after verifying that all actions the tissue bank took were effective in removing the likelihood that serious harm or death would occur or recur.

I. Informal Dispute Resolution (IDR).

(1) A tissue bank may request an IDR to dispute one or more deficiencies in a Statement of Deficiencies.

(2) The tissue bank shall submit the request for an IDR to the OHCQ within 10 calendar days of receiving the Statement of Deficiencies.

(3) The written request for an IDR shall:

(a) Fully describe the disagreement with the Statement of Deficiencies; and

(b) Include all accompanying evidence for the OHCQ's consideration.

(4) At the discretion of the OHCQ, the IDR may be held in person, by telephone, by video conference, or in writing.

(5) IDRs are informal in nature and may not be attended by legal counsel representing the tissue bank or the Department.

(6) The IDR process may not delay the effective date of any enforcement action.

(7) In the event a tissue bank requests an IDR for a Statement of Deficiencies written by a designee of the Department, the Department shall request the designee to participate in the IDR process.

(8) There is no appeal of the Department's decision in an IDR.

J. Process of Filing a Complaint. The tissue bank shall have a written process that describes how donors and recipients of tissue bank services are notified of how to file a complaint with the OHCQ and, if applicable, an accreditation organization.

.10 Tissue Bank Standards—Personnel.

A. (text unchanged)

B. Medical Director.

(1)—(2) (text unchanged)

(3) Responsibilities. The medical director shall *be responsible for all medical aspects of the tissue bank's operations and shall retain overall responsibility when a task is delegated to a designated qualified employee. The medical director or the designated qualified employee shall*:

(a)—(h) (text unchanged)

C. Technical Director.

(1) Qualifications. The technical director shall *be qualified by training and experience for the scope of activities being pursued and have*:

(a) **[**Hold an earned**]** *A* bachelor's or higher degree in medical technology or a biological science from an accredited college or university and be qualified by training and experience for the scope of activities conducted by the tissue bank; **[**or**]**

(b) **[**Hold an earned**]** *A* bachelor's degree in a discipline other than medical technology or a biological science from an accredited college or university and have 5 years of experience overseeing all technical aspects of tissue bank operations under the supervision of a medical director**[.]***; or*

(c) Licensure as a registered nurse in the state that the tissue bank is operating.

(2) Responsibilities. The technical director shall *oversee and be responsible for all technical aspects of the tissue bank's operations and shall retain overall responsibility when a task is delegated to a designated qualified employee. The technical director or designated qualified employee shall*:

(a)—(b) (text unchanged)

D. Technical Staff.

(1) Qualifications.

(a) (text unchanged)

(b) The technical director *or the designated qualified employee,* and medical director *or the designated qualified employee* shall train individual staff to accurately and reliably:

(i)—(ii) (text unchanged)

(2) Responsibilities.

(a) (text unchanged)

(b) A technical director *or the designated qualified employee* shall list and describe the duties and responsibilities of technical staff in written job descriptions.

(c)—(d) (text unchanged)

.11 Tissue Bank Standards — Testing to Minimize Disease Transmission.

A. Required Testing.

(1) General — All Donors. A **[**permittee**]** *permit holder* shall ensure that a prospective donor of tissue, including both leukocyte-rich and leukocyte-poor cell and tissue, intended to be used as an allograft is tested for biochemical, immunological, or serological evidence of:

(a)—(e) (text unchanged)

(2) Specific — Donors of Specific Tissue or Cell Types.

(a) In addition to those tests set forth in §A(1) of this regulation, a **[**permittee**]** *permit holder* shall ensure that a prospective donor of specific types of tissue are tested in accordance with the requirements set forth in §A(2)(b)—(c) of this regulation.

(b) Donors of Leukocyte-**[**rich**]** *Rich* Tissue. A **[**permittee**]** *permit holder* shall ensure that a prospective donor of a leukocyte-rich tissue, as defined in Regulation .03B of this chapter, intended to be used as an allograft, is tested for biochemical, immunological, or serological evidence of:

(i)—(iii) (text unchanged)

(c) Donors of Reproductive Tissue including Oocytes and Semen. In addition to those applicable tests set forth in §A(1) and (2)(a) of this regulation, a **[**permittee**]** *permit holder* shall ensure that a prospective donor of reproductive tissue, as defined in Regulation .03B of this chapter, intended to be used as an allograft, is tested for biochemical, immunological, or serological evidence of:

(i)—(ii) (text unchanged)

B.—C. (text unchanged)

RYAN B. MORAN, DrPH, MHSA
Acting Secretary of Health