

MARYLAND REGISTER

Proposed Action on Regulations

Transmittal Sheet PROPOSED OR REPROPOSED Actions on Regulations	Date Filed with AELR Committee	TO BE COMPLETED BY DSD
	04/25/2016	Date Filed with Division of State Documents
		Document Number
		Date of Publication in MD Register

1. Desired date of publication in Maryland Register: 6/10/2016

2. COMAR Codification

Title Subtitle Chapter Regulation

10 50 01 04

3. Name of Promulgating Authority

Department of Health and Mental Hygiene

4. Name of Regulations Coordinator

Michele Phinney

Telephone Number

410-767-5623

Mailing Address

201 W. Preston Street

City State Zip Code

Baltimore MD 21201

Email

michele.phinney@maryland.gov

5. Name of Person to Call About this Document

Amanda Thomas

Telephone No.

410-402-8054

Email Address

amanda.thomas@maryland.gov

Title 10
DEPARTMENT OF HEALTH AND MENTAL HYGIENE
Subtitle 50 TISSUE BANKS

10.50.01 Tissue Banks

Authority: Health-General Article, §17-302, Annotated Code of Maryland

Notice of Proposed Action

[]

The Secretary of Health and Mental Hygiene proposes to amend Regulation .04 under COMAR 10.50.01 Tissue Banks.

Statement of Purpose

The purpose of this action is to amend and update the edition of the following incorporated by reference documents:

- 1) Standards for Tissue Banking; and
- 2) Standards for Blood Banks and Transfusion Services

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

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 Michele Phinney, Director, Office of Regulation and Policy Coordination, Department of Health and Mental Hygiene, West Preston Street, Room 512, Baltimore, MD 21201, or call 410-767-6499; TTY:800-735-2258, or email to dhmh.regs@maryland.gov, or fax to 410-767-6483. Comments will be accepted through July 11, 2016. A public hearing has not been scheduled.

Economic Impact Statement Part C

- A. Fiscal Year in which regulations will become effective: FY 2017
- B. Does the budget for the fiscal year in which regulations become effective contain funds to implement the regulations?
- C. If 'yes', state whether general, special (exact name), or federal funds will be used:
- D. If 'no', identify the source(s) of funds necessary for implementation of these regulations:
- E. If these regulations have no economic impact under Part A, indicate reason briefly:
The sole purpose of this regulation is to update the required reference materials to newer editions to ensure that the correct standards are being followed. After review and discussion by the LAC, the standards in the updated editions have not changed significantly enough to cause a burden for Tissue Banks to comply. Contrarily, most tissue banks as well as OHCQ have the updated reference materials. OHCQ's intent is to amend the regulation to bring it up to date.
- F. If these regulations have minimal or no economic impact on small businesses under Part B, indicate the reason and attach small business worksheet.
See E above.
- G. Small Business Worksheet:

Attached Document:

Title 10

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 50 TISSUE BANKS

10.50.01 Tissue Banks

Authority: Health-General Article, §17-302, Annotated Code of Maryland

10.50.01.04 (1/12/16)

.04 Incorporation by Reference.

- A. (text unchanged)
- B. Documents Incorporated.
- (1) Standards for Tissue Banking (American Association of Tissue Banks, [2002] *13th* 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, [2003] *29th* Edition);
- (3)—(5) (text unchanged)

VAN T. MITCHELL

Secretary of Health and Mental Hygiene

**Incorporation by Reference
APPROVAL FORM**

Date: April 22, 2016
COMAR: 10.50.01.04B(1) and (2)

Michele Phinney, Director
DHMH – Office of Regulation and Policy Coordination
201 West Preston Street, Room 512
Baltimore, MD 21201

Dear Michele:

The following documents are approved for incorporation by reference:

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

(2) Standards for Blood Banks and Transfusion Services (American Association of Blood Banks, 29th Edition).

Please note the following special instructions: None

Attach a copy of this approval form when submitting an emergency or proposed regulation to the AELR Committee and when submitting a proposed regulation to DSD for publication in the Maryland Register. If submitting through ELF, include as part of the attachment.

Any future changes to the incorporated documents do not automatically become part of the regulation. If there are subsequent changes to the incorporated documents, and the agency wishes those changes to become a part of its regulations, the agency must amend the regulation incorporating the documents.

Please call us if you have any questions.

Sincerely,
Gail S. Klakring
Senior Editor