

**Maryland General Assembly
Department of Legislative Services**

**Proposed Regulation
Department of Health and Mental Hygiene
(DLS Control No. 16-063)**

Overview and Legal and Fiscal Impact

The regulation incorporates by reference up-to-date standards for tissue banks, blood banks, and transfusion services.

The regulation presents no legal issues of concern.

There is no fiscal impact on State or local agencies.

Regulation of COMAR Affected

Department of Health and Mental Hygiene:

Tissue Banks: Tissue Banks: COMAR 10.50.01.04

Legal Analysis

Summary of Regulation

The regulation incorporates by reference:

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

Legal Issues

The regulation presents no legal issues of concern.

Statutory Authority and Legislative Intent

The Department of Health and Mental Hygiene cites § 17-302 of the Health – General Article as statutory authority for the regulation. Section 17-302 requires the Secretary of Health and Mental Hygiene to adopt regulations that set standards for tissue banks to assure the citizens of the State that tissue banks provide safe and reliable services.

This authority is correct and complete. The regulation complies with the legislative intent of the law.

Fiscal Analysis

There is no fiscal impact on State or local agencies.

Agency Estimate of Projected Fiscal Impact

The regulation updates documents incorporated by reference for standards for tissue banking, blood banks, and transfusion services to the most recent applicable versions. The department advises that the regulation has no impact on State or local governments. The Department of Legislative Services concurs.

Impact on Budget

There is no impact on the State operating or capital budget.

Agency Estimate of Projected Small Business Impact

The department advises that the regulation has minimal or no economic impact on small businesses in the State. The Department of Legislative Services concurs.

Contact Information

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