

**Maryland General Assembly  
Department of Legislative Services**

**Proposed Regulation  
Department of Health and Mental Hygiene  
(DLS Control No. 15-243)**

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## **Overview and Legal and Fiscal Impact**

The regulation reduces the initial application fee and the biennial renewal license fee from \$200 to \$100 for a letter of exception for a physician office laboratory or a point-of-care laboratory and for Limited Testing for Rare Diseases.

The regulation presents no legal issues of concern.

General fund revenues decrease by approximately \$173,100 annually from reduced licensing fees.

## **Regulation of COMAR Affected**

### **Department of Health and Mental Hygiene:**

Laboratories: Medical Laboratories – Fees: COMAR 10.10.04.02

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## **Legal Analysis**

### **Background**

On September 15, 2015, Governor Larry Hogan announced a plan to reduce or eliminate a number of fees across State government. This regulation is part of that plan. Additional information regarding Governor Hogan's fee reduction initiative may be found [here](#).

### **Summary of Regulation**

The regulation reduces the initial application fee and biennial renewal license fee from \$200 to \$100 for a letter of exception for a physician office laboratory or a point-of-care laboratory and for Limited Testing for Rare Diseases. A physician office laboratory is a medical laboratory operated by a single practice of medicine, individually or collectively by one or more physicians that is used solely as an adjunct to the care of patients of the practice. A point-of-care laboratory is a laboratory operated as part of, or in association with, a medical care facility, such as a hospital, nursing home, community health center, health maintenance organization, county or municipal health department, or a pharmacy.

For an entity that qualifies for a letter of exception but also performs one or more tests that require a permit, the regulation eliminates the requirement to pay the \$200 fee for a letter of

exception, but retains the requirement to pay a \$200 fee for each discipline in which the laboratory offers to perform or performs nonexcepted tests.

### **Legal Issues**

The regulation presents no legal issues of concern.

### **Statutory Authority and Legislative Intent**

The Department of Health and Mental Hygiene cites §§ 17-202, 17-204, 17-205, 17-207, 17-209, 17-502, 17-503, and 17-506 of the Health – General Article as statutory authority for the regulation. Section 17-202(a) requires the Secretary of Health and Mental Hygiene to adopt regulations that set standards and requirements for medical laboratories.

Section 17-204 requires the Secretary to set licensing fees in accordance with § 2-104 of the article. Section 2-104(n) authorizes the Secretary to “adopt regulations establishing fees not to exceed an amount sufficient to cover the administrative costs associated with: (1) [i]nspections or investigations carried out under this article; and (2) [p]ermits, licenses, certifications, or registrations issued under this article.” Department staff advise that the reduced fee still covers administrative costs associated with the letter of exception.

Section 17-205(b) requires the Secretary to issue a letter of exception to a laboratory that: (1) performs only limited medical laboratory tests or examinations as defined in regulations adopted by the Secretary; and (2) meets the exception requirements in regulations adopted by the Secretary. Sections 17-207 and 17-209 establish requirements for medical laboratory license applications and renewals.

Sections 17-502, 17-503, and 17-506 establish requirements for cholesterol testing permits. These sections do not relate to the proposed regulation.

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

### **Technical Corrections and Special Notes**

The regulation originally submitted contained errors in the text of the current regulation. The department has submitted revised text that corrects the errors.

### **Fiscal Analysis**

General fund revenues decrease by approximately \$173,100 annually from reduced licensing fees.

## **Agency Estimate of Projected Fiscal Impact**

The department advises that general fund revenues decrease by approximately \$173,100 annually. The Department of Legislative Services concurs. This estimate reflects the decrease in the biennial fee for a letter of exception for a physician from \$200 to \$100 for an office laboratory or a point-of-care laboratory and for limited testing for rare diseases. The fee reduction affects approximately 3,462 providers. Renewals are processed on a rolling basis and approximately one-half are processed every year. Thus, there should be a relatively consistent annual fiscal impact.

## **Impact on Budget**

Although general fund revenues decline, there is no material impact on the State operating or capital budget.

## **Agency Estimate of Projected Small Business Impact**

The department advises that the proposed action has minimal or no economic impact on small businesses. The Department of Legislative Service concurs.

## **Additional Comments**

The department is authorized to establish fees at a level not to exceed an amount sufficient to cover administrative costs. There is no requirement that the department cover costs. The department estimates that the proposed fee level is adequate to cover administrative costs. However, because these administrative costs are general funded, it is unclear to what extent the current fees cover costs associated with issuing letters of exception. Further, issuing letters of exception is only one of a large number of functions carried out by the affected unit. Regardless, staffing is not expected to change as a result of the regulation.

## **Contact Information**

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