

Department of Legislative Services
Maryland General Assembly
2005 Session

FISCAL AND POLICY NOTE

Revised

Senate Bill 621 (Chairman, Education, Health, and Environmental Affairs Committee)
(By Request – Departmental – Health and Mental Hygiene)

Education, Health, and Environmental Affairs

Health and Government Operations

Department of Health and Mental Hygiene - Medical Laboratories - Retests and
Public Notification

This departmental bill provides that if a medical laboratory provided erroneous or questionable test results that pose a threat to the health and safety of patients, the Secretary of Health and Mental Hygiene may order the laboratory to (1) notify physicians or other individuals who ordered the tests of the erroneous or questionable test results; and (2) take any additional measures necessary to reduce or eliminate the threat to the health and safety of patients, including notifying patients and offering retests. A laboratory that does not comply with the Secretary's order is subject to a civil penalty of up to \$1,000 for each day of noncompliance after the order's deadline, up to a maximum penalty of \$50,000, instead of or in addition to any other sanction. Before a civil penalty is imposed, the licensee must be given an opportunity for a hearing.

The bill takes effect July 1, 2005.

Fiscal Summary

State Effect: Potential minimal increase in general fund revenues due to the bill's civil penalty provisions. No effect on expenditures.

Local Effect: Potential minimal increase in revenues due to the bill's civil penalty provisions. No effect on expenditures.

Small Business Effect: The Department of Health and Mental Hygiene (DHMH) has determined that this bill has minimal or no impact on small business (attached). Legislative Services concurs with this assessment. The attached assessment does not reflect amendments to the bill.

Analysis

Current Law: The Secretary of Health and Mental Hygiene can deny a medical laboratory license to any applicant or suspend, revoke, or limit a license or the authority to offer or perform any service or test if the laboratory, its director, or other personnel do not meet State standards and requirements. If the Secretary finds that a licensed laboratory no longer meets State standards and requirements, the Secretary may impose a directed plan of correction or limit the testing authorized by the licensee instead of suspending or revoking a license. Before a license is denied, suspended, or revoked, an applicant or licensee must be given an opportunity for a hearing.

Background: There are 4,384 licensed medical laboratories in Maryland. DHMH currently does not have the authority to order a laboratory to conduct retesting or to provide notification to physicians, patients, and the public in the event of testing errors. This lack of authority was brought to light during the recent problems at Maryland General Hospital. Hospital laboratory workers who warned the hospital of problems at the lab had their concerns ignored and were threatened with termination. Problems with the hospital's lab resulted in more than 450 individuals receiving HIV and hepatitis C results although the results might have been invalid, *The Baltimore Sun* reported.

State Revenues: General fund revenues could increase minimally under the bill's civil monetary penalty provisions for those cases heard in the District Court.

Local Revenues: Revenues could increase minimally under the bill's monetary penalty provisions for those cases heard in the circuit courts.

Additional Information

Prior Introductions: None.

Cross File: None.

Information Source(s): Department of Health and Mental Hygiene, Department of Legislative Services

Fiscal Note History: First Reader - March 7, 2005
m/jr Revised - Senate Third Reader - March 29, 2005

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