

Department of Legislative Services
 Maryland General Assembly
 2005 Session

FISCAL AND POLICY NOTE
Revised

House Bill 351 (Delegate Donoghue, *et al.*)
 Economic Matters and Health and Education, Health, and Environmental Affairs
 Government Operations

Medical Laboratories - Whistleblower Protection and Regulation

This bill provides whistleblower protections for medical laboratory employees.

Fiscal Summary

State Effect: The Department of Health and Mental Hygiene (DHMH) general fund expenditures could increase by \$49,700 in FY 2006 to hire one laboratory investigator. Future years reflect annualization and inflation. The civil and criminal penalty provisions of this bill are not expected to significantly affect State finances or operations.

(in dollars)	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010
GF Revenue	-	-	-	-	-
GF Expenditure	49,700	61,000	64,400	68,000	71,900
Net Effect	(\$49,700)	(\$61,000)	(\$64,400)	(\$68,000)	(\$71,900)

Note:() = decrease; GF = general funds; FF = federal funds; SF = special funds; - = indeterminate effect

Local Effect: The civil and criminal penalty provisions of this bill are not expected to significantly affect local finances or operations.

Small Business Effect: Meaningful for any small business medical laboratory upon which a civil or criminal penalty would be imposed.

Analysis

Bill Summary: A medical laboratory may not take or refuse to take any personnel action as a reprisal against an employee because the employee:

- discloses or threatens to disclose to a supervisor, DHMH, or an accrediting organization any activity, policy, or practice of the employer that violates a law, rule, or regulation regarding a laboratory's clinical diagnostic tests that the employee reasonably and in good faith believes evidences a substantial and specific danger to public health or safety or a violation of the standards and requirements for medical laboratories in Maryland;
- provides information to or testifies before any public body conducting an investigation, hearing, or inquiry into the violation; or
- objects to, or refuses to participate in, any activity, policy, or practice that is a violation.

Once the Secretary receives a report of a medical laboratory's noncompliance with a law, rule, or regulation, the Secretary must promptly determine whether to investigate the report. If a report is made anonymously, the Secretary may not disclose to a medical laboratory the identity of the employee making the report. If the Secretary decides to investigate the report, the inspection must be unannounced.

An employee subject to a personnel action in violation of the bill can institute a civil action in the county where the alleged violation occurred, the employee resides, or the medical laboratory maintains its principal offices in Maryland.

Employees may bring a civil action within one year after the alleged violation occurred or within one year after the employee first became aware of the alleged violation. A court may: (1) issue an injunction to restrain continued violation; (2) reinstate the employee to the same or equivalent position held before the violation; (3) remove any adverse personnel record entries based on or related to the violation; (4) reinstate full fringe benefits and seniority rights; (5) require compensation for lost wages, benefits, and other remuneration; and (6) assess reasonable attorney's fees and other litigation expenses against the medical laboratory if the employee prevails, or against the employee if the court determines that the employee brought the action in bad faith and without basis in law or fact.

It is a defense under an action brought under this bill that the personnel action was based on grounds other than the employee's exercise of any protected rights.

DHMH regulations must require each medical laboratory to conspicuously post a notice to employees that indicates how to report noncompliance with medical laboratory standards and requirements, including deficiencies regarding testing, quality, and inadequately trained personnel. The Secretary may waive the notice requirement for a

medical laboratory accredited by an organization approved by the Secretary if the organization has an equivalent requirement.

By December 15 each year, the Secretary must submit a report to the Governor; the Senate Education, Health, and Environmental Affairs Committee; and the House Health and Government Operations Committee regarding:

- the number of licensed medical laboratories in Maryland;
- the number of discoveries made as a result of the investigations;
- the number of reports received;
- the steps taken to correct any discoveries or reports identified and the promptness with which the actions were taken; and
- the number of actions taken under the penalty provisions for medical laboratories.

The Secretary may enter into an information sharing agreement with an approved accrediting organization to ensure ongoing communication that includes information sharing regarding a discovery of noncompliance or other violations.

The bill increases the maximum misdemeanor fines for a violation of any medical laboratory provision: for a first offense, from \$100 to \$5,000; for each subsequent offense, from \$500 to \$10,000.

Current Law: DHMH conducts inspections of each medical laboratory for which a license is sought and periodically inspects licensees. The Secretary may inspect a medical laboratory accredited by an organization for a complaint investigation or to validate the findings of the accreditation organization.

DHMH's Office of Health Care Quality (OHCQ) licenses medical laboratories in Maryland operated by the private sector and by the State, a county, or a municipal corporation. As a condition of licensure, laboratories are subject to inspections to ensure compliance with State statutes and regulations. OHCQ must either conduct or oversee the inspection itself or may accept a private organization's accreditation of the laboratory if the organization's standards are equivalent to the State's standards. Laboratories are subject to various sanctions for violations of statute and regulations.

Chapter 397 of 2004 prohibits employers that enter into contracts with a unit of State government under the State Finance and Procurement Article from taking personnel actions against an employee as a reprisal for whistleblowing.

The Maryland Whistleblower Act of 1980 protects Executive Branch employees from retaliation for reporting violations of State law. The law applies only to an employee in the Executive Branch, including units with independent personnel systems. The Act does not apply to State contractors.

Background: There are 4,384 licensed medical laboratories in Maryland. Congressman Elijah E. Cummings introduced a bill that would have provided whistleblower protection to employees of clinical laboratories who provide services under Medicare in October 2004. No action was taken on the bill before the 108th Congress ended.

Maryland General 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.

In a September 7, 2004 letter to Representative Cummings, the College of American Pathologists (CAP), an organization that inspects and accredits medical laboratories, stated that it will instruct each laboratory it accredits to post signs provided by the college in a prominent location that makes it clear to laboratory employees that they may use a toll-free phone number to confidentially report to the college any quality or safety concerns regarding laboratory operations that they may have. In a December 3, 2004 letter to Representative Cummings, the college stated that it has instituted a policy that provides for revoking CAP accreditation if individuals making complaints against a laboratory are harassed or threatened. The college also has mandated structured interaction between inspection teams and bench level laboratory employees to ascertain any personal concerns regarding quality.

State Revenues: The civil and criminal penalty provisions of this bill are not expected to significantly affect State revenues.

State Expenditures: General fund expenditures could increase by an estimated \$49,672 in fiscal 2006, which accounts for the bill's 90-day start-up delay. This estimate reflects the cost of hiring one laboratory science surveyor to inspect medical laboratories. Since the small laboratories located within doctors' offices typically have erratic hours of operation, it is assumed that visiting those laboratories unannounced will result in an inspector making a few visits before being able to conduct an inspection. It includes salaries, fringe benefits, one-time start-up costs, travel expenses, and ongoing operating expenses.

Salaries and Fringe Benefits	\$39,631
Operating Expenses	<u>10,041</u>
Total FY 2006 State Expenditures	\$49,672

Future year expenditures reflect: (1) full salaries with 4.6% annual increases and 3% employee turnover; and (2) 1% annual increases in ongoing operating expenses. The civil penalty provisions of this bill are not expected to significantly affect State expenditures.

The civil and criminal penalty provisions of this bill are not expected to significantly affect State expenditures.

Local Revenues: The civil and criminal penalty provisions of this bill are not expected to significantly affect local revenues.

Local Expenditures: The civil and criminal penalty provisions of this bill are not expected to significantly affect local expenditures.

Additional Comments: SB 250, a similar bill, was introduced this session.

Additional Information

Prior Introductions: None.

Cross File: None.

Information Source(s): Judiciary (Administrative Office of the Courts), Department of Health and Mental Hygiene, Department of Legislative Services

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