

Department of Legislative Services
Maryland General Assembly
2005 Session

FISCAL AND POLICY NOTE
Revised

Senate Bill 250 (Senator Hollinger, *et al.*)
(Chair, Education, Health, and Environmental Affairs Committee)
Education, Health, and Environmental Affairs Economic Matters and Health and
Government Operations

Public Health - Medical Laboratories - Inspection, Information Sharing, and
Whistleblower Protection

This bill prevents a medical laboratory from taking an adverse employment action against an employee who discloses specified information to the Secretary of Health and Mental Hygiene. All medical laboratory inspections conducted by the Department of Health and Mental Hygiene (DHMH) must be unannounced except under certain conditions. The bill establishes a maximum \$2,000 civil penalty that may be imposed against a person who notifies, or causes to be notified, a medical laboratory of the time or date the unannounced inspection is scheduled to be conducted. The bill increases the maximum misdemeanor fine for a violation of any medical laboratory provision. It expands the scope of DHMH's Laboratory Advisory Committee, repeals its membership, and requires the appointment of new members.

The bill takes effect July 1, 2005.

Fiscal Summary

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

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: This bill allows a person who works in a medical laboratory to disclose information to the Secretary of Health and Mental Hygiene that the person reasonably and in good faith believes evidences: (1) a substantial and specific danger to public health or safety; or (2) a violation of the standards and requirements for medical laboratories in the State. Medical laboratories may not discriminate or retaliate against a person who works in the medical laboratory, or take any other adverse employment action, because of the disclosure or because the person agreed to cooperate with an investigation of the laboratory.

A person who is subject to an adverse employment action for disclosing information about the alleged offenses or for participating in an investigation of the alleged offenses may institute a civil action in the county where the alleged violation occurred, the person resides, or the medical laboratory maintains its principal office in the State.

Employees must bring a civil action within one year after the alleged violation occurred. A court may: (1) issue an injunction to restrain continued violation of the prohibition against taking adverse employment action against a medical laboratory worker; (2) reinstate the person to the same or equivalent position held before the violation; (3) remove any adverse personnel record entries based on or related to the violation of the prohibition against taking adverse employment action against a medical laboratory worker; (4) reinstate full fringe benefits and seniority rights; (5) require compensation for lost wages, benefits, and other remuneration; (6) award the costs of litigation and reasonable attorney's fees to the prevailing person; and (7) award any other appropriate damages or relief.

If the person makes a report anonymously, the Secretary may not disclose the person's identity.

The bill allows the Secretary to conduct an announced inspection if the total volume of tests conducted by the medical laboratory is less than 25,000 per year or the Secretary determines that an announced inspection is warranted.

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

The Secretary must develop and disseminate a document informing persons who work in a medical laboratory of how to report instances of noncompliance or other violations of the State's medical laboratories' standards and requirements. A medical laboratory must post this document in a conspicuous place. The Secretary may waive the posting requirement for a medical laboratory accredited by an organization approved by the Secretary if the accrediting organization has an equivalent requirement.

Additionally, the Secretary must enter into an information sharing agreement with an approved accrediting organization to ensure ongoing communication that includes information sharing regarding: (1) a discovery of noncompliance or other violation of regulations setting standards and requirements for medical laboratory inspections and medical laboratory accreditation provisions in statute; (2) the bill's provisions regarding a person who works in a laboratory disclosing information about a laboratory's alleged violations; and (3) a complaint filed by a consumer of services of a laboratory, a consumer's family member, a family member of a person who works in a laboratory, or other source.

Laboratory Advisory Committee

The bill expands the scope of DHMH's Laboratory Advisory Committee to require the committee to make recommendations to the Secretary regarding: (1) matters relating to the implementation of standards, inspections, and accreditation of medical and cytology laboratories; and (2) issues relating to quality of care and services performed by medical laboratories in Maryland.

The bill repeals the current committee membership and requires the committee to consist of the following individuals: one DHMH representative; one pathologist from a hospital laboratory; one pathologist from a free-standing independent laboratory; one physician from a laboratory that conducts fewer than 25,000 tests per year; three medical technologists who work in a medical laboratory; one representative from each approved accrediting organization; and two consumers, one of whom the Secretary must appoint to serve as the committee's chair.

Additionally, the bill repeals the Secretary's authority to appoint any other individuals or representatives at the Secretary's discretion and repeals the requirement that the Secretary must designate a committee chair every two years.

The Secretary must report to the Governor; the Senate Education, Health, and Environmental Affairs Committee; and the House Health and Government Operations Committee by December 15 of each year on: (1) the number of licensed medical laboratories in Maryland; (2) the number of discoveries made as a result of unannounced

medical laboratory inspections and the medical laboratory accreditation process; (3) the number of reports received by medical laboratory employees of alleged violations under this bill; (4) the steps taken to correct any discoveries or reports identified by the Secretary; and (5) the number of criminal or civil actions taken for medical laboratories' violations.

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 they comply 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.

The Secretary must establish a Laboratory Advisory Committee to advise the Secretary on matters relating to the implementation of the provisions relating to the implementation of standards, inspections, and accreditation of medical and cytology laboratories. The committee must consist of: (1) certain representatives appointed biennially from a list of eligible individuals submitted by the Medical and Chirurgical Faculty of Maryland; and (2) one representative of the Health Industry Manufacturers Association. The Secretary may appoint any other individuals or representatives at the Secretary's discretion. The Secretary must designate the committee's chairman every two years.

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 being fired. 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 Rep. 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.

DHMH reports that in most physicians' office laboratories, testing may not be conducted daily and the laboratory technologist may not be available on a daily basis. When conducting inspections, DHMH asserts that it is crucial that appropriate laboratory employees are present and appropriate laboratory functions are taking place.

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

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 Information

Prior Introductions: None.

Cross File: None.

Information Source(s): Judiciary (Administrative Office of the Courts); Department of Health and Mental Hygiene; “Oversight of labs at hospitals dissected: Ties with surveyors contributed to problems such as Md. General’s,” *The Baltimore Sun*, July 8, 2004; “Lab workers warned Md. General 2 years ago: Hospital’s managers ignored them, letter says,” *The Baltimore Sun*, April 22, 2004; College of American Pathologists; Department of Legislative Services

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