

Department of Legislative Services
Maryland General Assembly
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FISCAL AND POLICY NOTE

Senate Bill 758
Finance

(Senator Young, *et al.*)

**Department of Health and Mental Hygiene - Containment Laboratories -
Oversight**

This bill establishes a Containment Laboratory Oversight Division in the Department of Health and Mental Hygiene (DHMH). The bill specifies that the division must (1) be the sole unit of State government responsible for oversight of containment laboratories in the State; and (2) establish and enforce standards (for the location, design, maintenance, and operation of containment laboratories in the State) that protect the health and safety of laboratory workers, the public, and the environment from potentially harmful biological agents. In addition, the division must assume – from the Office of Laboratory Emergency Preparedness and Response (OLEPR) in DHMH – administration of DHMH’s Biological Agents Registry Program. The bill also establishes licensing and inspection requirements for containment laboratories. Additionally, the bill requires the Governor to establish a Containment Laboratory Advisory Committee (to be staffed by DHMH) to advise the Secretary of Health and Mental Hygiene on matters related to implementation of the bill. DHMH must adopt specified regulations to implement the bill.

Fiscal Summary

State Effect: DHMH advises that general fund expenditures increase by more than \$1.2 million annually beginning in FY 2013. Legislative Services concurs that general fund expenditures increase significantly under the bill (and likely exceed \$1.0 million annually) but advises that exact costs cannot be reliably determined at this time, as discussed below. General fund expenditures are offset, in part, by general fund revenues due to licensing fees collected from containment laboratories beginning in FY 2014. Higher education expenditures may increase, beginning in FY 2014, for fees associated with any academic laboratory that may be subject to licensure under the bill.

Local Effect: None.

Small Business Effect: Potential meaningful for any small laboratories that are subject, under the bill, to additional licensing requirements and fees.

Analysis

Bill Summary: The bill defines “containment laboratory” as a private or academic laboratory that qualifies as a biosafety level-3 laboratory (*i.e.*, one that is used to work with biological agents that are transmitted through the air and can cause a potentially serious or lethal human disease) or a biosafety level-4 laboratory (*i.e.*, one that is used to work with biological agents that may be transmitted through the air and pose a high risk of life-threatening or lethal human disease for which no vaccine or therapy is available).

Regulations adopted by DHMH must:

- establish the standards and requirements for containment laboratories necessary to protect the health and safety of laboratory workers, the public, and the environment from potentially harmful biological agents;
- integrate and streamline under the jurisdiction of the division any containment laboratory oversight functions performed by any instrumentality, agency, or unit of State government, including the Biological Agents Registry Program, OLEPR, the Division of Labor and Industry (DLI), and the Maryland Department of the Environment (MDE);
- establish requirements for licensure as a containment laboratory;
- develop physical plant design basis standards for containment laboratories with guidance from the U.S. Centers for Disease Control and Prevention, the U.S. Department of Agriculture (USDA), specified societies and institutes, and local construction permitting jurisdictions;
- establish, in coordination with the Maryland Emergency Management Agency and local organizations for emergency management, uniform emergency notification and response procedures that State and local organizations for emergency management must follow during emergencies involving containment laboratories;
- establish, with input from laboratory researchers at the National Institutes of Health (NIH) and other research institutions in the State, standard protocols that containment laboratory researchers and staff must follow when working with biological agents; and
- establish penalties for violations of standards and requirements adopted under the bill.

Any design basis standards for containment laboratories adopted under the bill must apply only to new facilities or to existing facilities that increase in size by at least 10%.

On or after January 1, 2014, a facility must hold a license issued by the division before operating a containment laboratory in the State. An applicant for a license must submit an application as specified by the bill (and in regulations adopted under the bill). A license is valid for one year and may be renewed annually. The Secretary must set reasonable fees for the issuance and renewal of licenses.

The division may deny a license to any applicant or suspend or revoke a license if the facility fails to meet the standards or requirements established under the bill. Before taking any such action, however, the division must give the applicant or licensee notice and an opportunity for a hearing.

To ensure compliance with the standards and requirements established by the bill, the division must inspect each facility that applies for an initial or renewal license to operate a containment laboratory.

The bill establishes membership for the Containment Laboratory Advisory Committee and specifies that a member of the committee may not receive compensation for serving on the committee but is entitled to reimbursement for expenses.

Current Law/Background: Containment laboratories are currently regulated by the federal government, including the U.S. Public Health Service and USDA (depending on the type of biological agents at issue).

The Biological Agents Registry Program, which is currently administered by OLEPR, is required to identify the biological agents possessed and maintained by any person in the State and must contain any other information required by regulations adopted by DHMH. Such regulations must provide for the release of information in the registry to specified agencies as well as establish specified safeguards and reporting processes.

Criteria established by NIH for determining biosafety levels depart from those established by the bill in that they account for factors such as infectivity, the nature of work being done at the laboratory, and the probability of a severe outcome. According to DHMH, there are currently 16 biosafety level-3 and biosafety level-4 laboratories in the State, based on NIH's criteria. DHMH advises that dozens of laboratories that are classified as biosafety level-2 laboratories under NIH's criteria may be classified as biosafety level-3 or level-4 laboratories (and, therefore, as containment laboratories) under the bill.

State Fiscal Effect: The Office of Health Care Quality (OHCQ) in DHMH advises that it must hire five full-time employees and one half-time employee to survey and inspect containment laboratories and administer the Biological Agents Registry Program. However, Legislative Services notes that the bill requires the newly created Containment Laboratory Oversight Division to administer the Biological Agents Registry Program and be the sole unit of State government responsible for oversight of containment laboratories in the State. Thus, Legislative Services advises that all costs under the bill are borne by the division – not by OHCQ.

DHMH advises that general fund expenditures increase by more than \$1.2 annually beginning in fiscal 2013. This estimate reflects information technology costs as well as the hiring of 22 full-time employees to staff the Containment Laboratory Oversight Division and 3 full-time employees to replace OLEPR employees that currently perform dual duties for the Laboratories Administration. Legislative Services concurs that general fund expenditures increase significantly under the bill but advises that exact costs cannot be reliably determined at this time, and a portion of those costs will not be incurred until fiscal 2014 when licensing is required. For example, although DHMH advises that there are currently 16 laboratories in the State that are classified as either biosafety level-3 or level-4, it is unclear how many laboratories will be classified as containment laboratories under the bill. (DHMH's estimate assumes that 50 laboratories will be classified as containment laboratories under the bill.) In addition, Legislative Services assumes that the advisory committee established under the bill can assist substantially in fulfilling some of the duties specified in the bill, including the development of regulations. Furthermore, the full extent to which existing OLEPR staff can be shifted to the division is unclear. However, Legislative Services concurs that general fund expenditures under the bill are likely to be significant, given the bill's licensing and inspection requirements and the complex nature of the regulations required to be adopted and enforced.

Higher education expenditures may also increase beginning in fiscal 2014 to the extent that any laboratories within the University System of Maryland qualify as containment laboratories under the bill and are therefore subject to additional licensing requirements and fees.

General fund expenditures are offset, in part, by general fund revenues due to licensing fees collected from containment laboratories. Since the bill does not establish a special fund for this purpose, all funds are assumed to be general funds. The exact amount of revenues will depend on the number of containment laboratories and the fee amounts established by the department. Since laboratories do not have to be licensed before January 1, 2014, Legislative Services assumes that licensing activity (and related revenues) begin in fiscal 2014.

Small Business Effect: Maryland has a high density of private laboratories due to the State's proximity to associated federal laboratories. For example, the Maryland Department of Agriculture advises that a disproportionately large percentage of "select agent" facility inspections conducted by USDA are conducted in Maryland. Under the bill, small laboratories are subject to additional licensing requirements and fees. Moreover, because such laboratories are already regulated by the federal government, Legislative Services advises that the bill may subject the laboratories to requirements that are duplicative of (or in conflict with) existing federal requirements.

Additional Comments: The Williams-Steiger Occupational Safety and Health Act (OSHA) of 1970 requires the U.S. Department of Labor to establish a program "to assure so far as possible every working man and woman in the nation with safe and healthful working conditions." The Act specifies that states may elect to assume the responsibility for development and management of a state occupational safety and health program as long as the standards under the state program are "at least as effective as" OSHA standards. DLI, which is designated as the agency responsible for Maryland's Occupational Safety and Health Plan, advises that the bill's requirement for the newly established division to be the sole unit of State government responsible for oversight of containment laboratories is inconsistent with OSHA.

MDE advises that certain water testing laboratories may be reclassified as containment laboratories under the bill, potentially resulting in the discontinuation of microbial testing by those laboratories (and causing a potential shortage of certified laboratories for drinking water analysis in the State).

Additional Information

Prior Introductions: None.

Cross File: None.

Information Source(s): Baltimore, Garrett, and Montgomery counties; Maryland Department of Agriculture; Maryland Department of the Environment; Department of Health and Mental Hygiene; Department of Labor, Licensing, and Regulation; University System of Maryland; Department of Legislative Services

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