

Department of Legislative Services
 Maryland General Assembly
 2018 Session

FISCAL AND POLICY NOTE
First Reader

Senate Bill 392 (Senator Young)
 Finance

Maryland Department of Health - Biosafety Level 3 Laboratories

This bill requires the Maryland Department of Health (MDH) to develop and make available a standardized form to collect specified information from each biosafety level 3 laboratory (BSL-3 laboratory) in the State that does not work with federally regulated biological select agents and toxins or their products *and* is one of the following: (1) a commercial or for-profit laboratory; (2) owned by or part of a teaching hospital or an institution of postsecondary education; or (3) a privately funded biomedical research laboratory. Each affected BSL-3 laboratory must annually report required information to MDH and is subject to fine and penalty provisions for failing to do so. The bill also establishes reporting requirements for MDH and requires the department to develop a strategy to identify and notify affected BSL-3 laboratories.

Fiscal Summary

State Effect: General fund expenditures increase by \$39,300 in FY 2019 and by \$10,800 in FY 2020 for contractual staff. Minimal increase in general fund expenditures in future years for ongoing reporting requirements and outreach. The bill’s penalty provisions are not anticipated to significantly affect State finances.

(in dollars)	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023
Revenues	\$0	\$0	\$0	\$0	\$0
GF Expenditure	39,300	10,800	-	-	-
Net Effect	(\$39,300)	(\$10,800)	(-)	(-)	(-)

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

Local Effect: None. Local health officers and emergency management officials do not have any additional duties under the bill; however, they may benefit from knowing about BSL-3 laboratories in their jurisdictions.

Small Business Effect: Minimal.

Analysis

Bill Summary: A “BSL-3 laboratory” means a laboratory designated as a BSL-3 laboratory by the U.S. Centers for Disease Control and Prevention (CDC) and the U.S. Department of Agriculture Animal and Plant Health Inspection Service, as applicable, based on (1) usage of biological agents that may cause serious or potentially lethal disease after inhalation, ingestion, or absorption and (2) required biocontainment precautions.

Annually by September 30, each BSL-3 laboratory must report to MDH (1) the address of the laboratory; (2) the name, telephone number, and email address of a laboratory contact person; and (3) any other information required by MDH to determine the location of the laboratory. Annually by December 31, MDH must report (1) the number and location, in total and by jurisdiction, of BSL-3 laboratories in the State to the health officer and emergency management officials of each local jurisdiction and (2) the total number of BSL-3 laboratories in the State to the Governor and the General Assembly. Any other information that MDH collects from BSL-3 laboratories under the bill is confidential and not subject to inspection under the Public Information Act.

A BSL-3 laboratory that fails to report required information is guilty of a misdemeanor and, on conviction, is subject to a fine of up to \$100 for a first offense and up to \$500 for each subsequent conviction. Each day a violation continues after the first conviction is a subsequent offense. Additionally, a laboratory subject to the bill’s provisions that fails to report the required information is subject to an administrative fine of up to \$500.

MDH must develop a strategy to attempt to identify affected BSL-3 laboratories for the purpose of notifying the laboratories of the bill’s requirements. This strategy may rely on a number of listed sources.

Current Law/Background: There are four biosafety levels (1 through 4) that are defined based on infectivity, severity of disease, transmissibility, and the nature of the work being conducted. “Containment” or “biocontainment” means the microbiological practices, safety equipment, and facility safeguards that protect laboratory workers, the environment, and the public from exposure to infectious microorganisms and toxins that are handled and stored in the laboratory.

Containment laboratories are regulated by several federal government agencies, including the U.S. Public Health Service, the U.S. Department of Agriculture, and CDC (depending on the type of biological agents at issue). Additionally, the U.S. Department of Health and Human Services and CDC have published five editions of *Biosafety in Microbiological and Biomedical Laboratories*, an advisory document recommending best practices for the safe conduct of work in biomedical and clinical laboratories from a biosafety perspective.

However, according to the October 2013 *Report on the Health and Safety Issues Associated with High Containment Laboratories in the State of Maryland*, published by MDH, no government entity regulates or provides oversight of laboratories working with BSL-3 pathogens that are not on the “select agent” list (including *Mycobacterium tuberculosis* (tuberculosis), Middle East Respiratory Syndrome corona virus (MERS), *Hantavirus*, *St. Louis Encephalitis Virus*, *Western Equine Encephalitis Virus*, and others). Additionally, there is no federal or State regulatory standard requirement for nonselect agent research. Thus, there is no government entity tracking everyone who operates a BSL-3 laboratory or where those laboratories are located. Private BSL-3 research laboratories not working with select agents may adopt safety standards voluntarily, and they are self-policing.

In Maryland, MDH’s Office of Laboratory Emergency Preparedness and Response (OLEPR) administers the Biological Agents Registry Program. OLEPR must identify the biological agents possessed and maintained by any person in the State, and it must obtain any other information required by regulations adopted by MDH. Such regulations must provide for the release of information in the registry to specified agencies as well as establish specified safeguards and reporting processes.

State Expenditures: General fund expenditures increase by \$39,269 in fiscal 2019, which accounts for the bill’s October 1, 2018 effective date.

The MDH Laboratories Administration has determined that 2 regular part-time positions are needed to develop a comprehensive electronic questionnaire to collect the required information; design, develop, and maintain a database that holds the information; conduct outreach to and follow up with the affected laboratories; conduct risk assessments on each BSL-3 laboratory; and analyze received information. The Laboratories Administration further notes that there is no existing viable mechanism to identify BSL-3 laboratories in the State. Prior attempts to identify these laboratories via survey have been unsuccessful. Thus, MDH anticipates that a robust strategy of identification is necessary to successfully identify and elicit responses from affected BSL-3 laboratories in the State. Finally, the Laboratories Administration notes that it has lost 10 positions in recent years and has no capacity to absorb additional responsibilities under the bill.

The Department of Legislative Services (DLS) agrees that, given the Laboratories Administration’s fiscal and staffing constraints, and the robust implementation plan that MDH intends to pursue, the bill establishes additional responsibilities that cannot be absorbed by existing budgeted staff and resources. However, DLS advises that the bulk of the added responsibilities incurred by this legislation can be completed in the first year of implementation; thereafter, more minimal effort is required. Thus, this estimate reflects the cost of hiring one full-time contractual administrative officer to develop and make available a standardized form to obtain BSL-3 laboratory information, develop a strategy

to identify and notify affected BSL-3 laboratories, and fulfill the bill's initial reporting requirements. It includes a salary, fringe benefits, one-time start-up costs, and ongoing operating expenses.

Contractual Position	1
Salary and Fringe Benefits	\$33,910
Operating Expenses	<u>5,359</u>
Total FY 2019 State Expenditures	\$39,269

Future year expenditures reflect termination of the contractual employee in fiscal 2020. However, due to staffing constraints within the department, MDH needs contractual support each year when the report is due, accordingly minimal general fund expenditures continue in out-years for seasonal contractual support.

This estimate does not include any health insurance costs that could be incurred for specified contractual employees under the State's implementation of the federal Patient Protection and Affordable Care Act.

Additional Information

Prior Introductions: SB 400 of 2017 received an unfavorable report from the Senate Finance Committee. Its cross file, HB 1172 passed the House and received a first reading in the Senate Finance Committee, but no further action was taken. SB 700 of 2016 received an unfavorable report from the Senate Finance Committee. Its cross file, HB 699, passed the House with amendments and was referred to the Senate Rules Committee, but no further action was taken.

Cross File: Although designated as a cross file, HB 655 (Delegate K. Young, *et al.* - Health and Government Operations) is not identical.

Information Source(s): Maryland Association of County Health Officers; Baltimore City; Harford and Montgomery counties; University System of Maryland; Maryland Department of Agriculture; Maryland Department of the Environment; Maryland Department of Health; Department of State Police; Department of Legislative Services

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nb/jc

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