

Department of Legislative Services
 Maryland General Assembly
 2016 Session

FISCAL AND POLICY NOTE
First Reader

Senate Bill 700 (Senator Young)
 Finance

Department of Health and Mental Hygiene - Biosafety Level 3 Laboratories

This bill requires the Department of Health and Mental Hygiene (DHMH) to identify, locate, and collect relevant public health and safety information from each biosafety level 3 (BSL-3) laboratory in the State that (1) does not work with federally regulated biological select agents and toxins or their products and (2) is either a commercial or for-profit laboratory or is owned or is part of a teaching hospital or an institution of postsecondary education. Each affected BSL-3 laboratory must report required information to DHMH and is subject to fine and penalty provisions for failing to do so. The bill establishes reporting requirements for DHMH.

Fiscal Summary

State Effect: General fund expenditures for DHMH increase by \$47,600 in FY 2017 to hire two part-time contractual employees to devise an electronic questionnaire to obtain BSL-3 facility information, locate applicable laboratories, send the questionnaire, and establish a database to track the required information. Future years reflect minimal costs to fulfill the ongoing reporting requirement and elimination of the contractual employees. The bill’s penalty provisions are not anticipated to significantly affect State finances.

(in dollars)	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021
Revenues	\$0	\$0	\$0	\$0	\$0
GF Expenditure	47,600	16,800	-	-	-
Net Effect	(\$47,600)	(\$16,800)	(-)	(-)	(-)

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

Local Effect: None.

Small Business Effect: Minimal.

Analysis

Bill Summary: A “biosafety level 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.

BSL-3 laboratories must report any required information to DHMH. Annually, beginning on December 31, 2017, DHMH must report (1) the number and location, in total and by jurisdiction, of BSL-3 laboratories to the emergency management and public health officials of each local jurisdiction and (2) the total number of BSL-3 laboratories in the State to the Governor and the Generally Assembly. Any other information that DHMH collects from BSL-3 laboratories under the bill is confidential and not subject to inspection.

A BSL-3 laboratory that fails to report required information under the bill’s provisions 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.

Current Law/Background: There are four biosafety levels (1 through 4), which 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 the federal government by several 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, along with 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 DHMH, 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 these 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, DHMH’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 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.

State Expenditures:

DHMH Administrative Costs

General fund expenditures increase by \$47,562 in fiscal 2017, which accounts for the bill’s October 1, 2016 effective date. DHMH has determined that two regular part-time positions are needed to implement this bill. However, the Department of Legislative Services advises that most of the work associated with the bill must be undertaken within the first year or so and, thus, may be performed by contractual employees. This estimate reflects the cost of hiring one part-time (50%) contractual program administrator and one part-time (50%) contractual programmer to develop and send an electronic questionnaire, identify BSL-3 laboratories in the State, establish a database to track collected information, and compose the initial required reports by year-end 2017. It includes salaries, fringe benefits, one-time start-up costs, rent, and operating expenses.

	<u>FY 2017</u>
Contractual Positions	1.0
Salaries and Fringe Benefits	\$36,184
Operating Expenses	<u>11,378</u>
Total FY 2017 State Expenditures	\$47,562

Fiscal 2018 expenditures reflect part-time salaries (three months for the programmer and six months for the administrator) and then elimination of the contractual staff. It is assumed that the workload in future years is significantly lower as most laboratories will have been identified in the first year and are required to report on their own under the bill, the database

will already be established, and the electronic questionnaire will already be developed. In January 2018, after the first required reports have been developed and submitted, this estimate assumes existing staff may absorb residual duties associated with the bill; even so, minimal additional costs may be incurred each year to assist in compiling each set of annual reports.

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.

Potential Impact on the University System of Maryland

The University System of Maryland (USM) advises that it currently reports similar information to the Maryland Biological Agents Registry and that it can provide similar information to DHMH with existing staff resources. However, USM advises that, depending on the breadth of information that is determined "relevant" by DHMH, this requirement may be more burdensome.

Additional Information

Prior Introductions: HB 665 of 2015, a similar bill, was withdrawn after a hearing in the House Health and Government Operations Committee. Its cross file, SB 675, received a hearing in the Senate Finance Committee, but no further action was taken.

Cross File: HB 699 (Delegates K. Young and Krimm) - Health and Government Operations.

Information Source(s): Maryland Association of County Health Officers, University System of Maryland, Maryland Department of Agriculture, Maryland Department of the Environment, Department of Health and Mental Hygiene, Department of State Police, Department of Legislative Services

Fiscal Note History: First Reader - March 9, 2016
md/ljm

Analysis by: Kathleen P. Kennedy

Direct Inquiries to:
(410) 946-5510
(301) 970-5510