

Department of Legislative Services
Maryland General Assembly
2015 Session

FISCAL AND POLICY NOTE

House Bill 665 (Delegates K. Young and Krimm)
Health and Government Operations

**Department of Health and Mental Hygiene - Biosafety Level 3 (BSL-3)
Laboratory Safety Program**

This bill establishes the Biosafety Level 3 (BSL-3) Laboratory Safety Program within the Department of Health and Mental Hygiene (DHMH) and requires DHMH to identify both BSL-3 laboratories in the State that do not work with federally regulated biological select agents and toxins or their products and their location. DHMH also has to collect information it considers relevant to safety issues applicable to BSL-3 laboratories. The bill establishes reporting requirements for BSL-3 laboratories and DHMH. The bill also establishes fine and penalty provisions for persons who violate provisions of the bill.

Fiscal Summary

State Effect: No material fiscal impact. DHMH can devise an electronic questionnaire to obtain BSL-3 facility information, send the questionnaire to applicable laboratories, compile the required information, and compose the required report within existing budgeted resources. The penalty provisions are not anticipated to significantly affect State finances.

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 federal Centers for Disease Control and Prevention (CDC) based

on (1) usage of bio-agents that may cause serious or potentially lethal disease after inhalation and (2) required biocontainment precautions.

BSL-3 laboratories must report any required information to DHMH. By December 31 annually, DHMH must then report to the General Assembly and appropriate local jurisdictions (1) the number of BSL-3 laboratories that do not work with federally regulated biological select agents and toxins or their products and (2) the locations of these laboratories. Nonaggregated information prepared for or maintained by the program is confidential and not subject to certain inspection provisions.

A person who violates the provisions of the bill is guilty of a misdemeanor and, on conviction, subject to a fine of up to \$100 for the first offense and up to \$500 for each subsequent conviction for a violation of the same provision. Each day a violation is continued after the first conviction is a subsequent offense.

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) it 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.

Additional Information

Prior Introductions: None.

Cross File: SB 675 (Senator Young) - Finance.

Information Source(s): Maryland Department of Agriculture, Maryland Department of the Environment, Department of Health and Mental Hygiene, Department of State Police, University System of Maryland, U.S. Centers for Disease Control and Prevention, U.S. Department of Agriculture, U.S. Department of Health and Human Services, Department of Legislative Services

Fiscal Note History: First Reader - March 10, 2015
min/ljm

Analysis by: Kathleen P. Kennedy

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