Department of Legislative Services

Maryland General Assembly
2016 Session

FISCAL AND POLICY NOTE
Third Reader - Revised

House Bill 699 (Delegate K. Young, *et al.*)
Health and Government Operations Rules

Department of Health and Mental Hygiene - Biosafety Level 3 Laboratories

This bill requires the Department of Health and Mental Hygiene (DHMH) to develop and make available a standardized form to collect specified information from each biosafety level 3 (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, by September 30, 2017, and annually thereafter, report required information to DHMH and is subject to fine and penalty provisions for failing to do so. The bill also establishes reporting requirements for DHMH and requires the department to develop a strategy to identify and notify affected BSL-3 laboratories.

Fiscal Summary

State Effect: No material fiscal impact. DHMH can 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 reporting requirements with existing staff, as discussed below. The bill's penalty provisions are not anticipated to significantly affect State finances.

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 "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.

Annually, beginning September 30, 2017, BSL-3 laboratories must report (1) the address of the laboratory; (2) the name, telephone number, and email address of a laboratory contact person; and (3) any other required information to DHMH. Annually, beginning December 31, 2017, DHMH must report (1) the number and location, in total and by jurisdiction, of BSL-3 laboratories 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 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.

DHMH must develop a strategy to attempt to identify affected BSL-3 laboratories and notify 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), 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 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 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's Laboratories Administration has determined that two regular part-time positions are needed to implement the bill's requirements including to develop a comprehensive electronic questionnaire to collect the required information; design, develop, and maintain a database that holds the information; conduct outreach and follow-up to the affected laboratories; and analyze received information.

However, the Department of Legislative Services (DLS) disagrees that the bill's requirements alone justify hiring additional staff. The onus of reporting the required information falls on the laboratories, not DHMH. Additionally, the department is authorized to utilize an already developed list of affected laboratories as part of the required outreach strategy. Further, there is no requirement to develop an electronic questionnaire or database. Laboratories are only required to provide address and contact information, which DLS assumes the department can track with minimal effort or staff time. Finally, the reporting requirement requires DHMH to compile information submitted, not to develop additional content or conduct any extensive outreach, etc. Thus, DLS advises that the bill likely has no material impact on expenditures and does not require additional staff.

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: SB 700 (Senator Young) - Finance.

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

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