

Department of Legislative Services  
Maryland General Assembly  
2020 Session

FISCAL AND POLICY NOTE  
Third Reader - Revised

House Bill 580

(Frederick County Delegation)

Health and Government Operations

Finance

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Maryland Department of Health – Biosafety Level 3 Laboratories in Frederick  
County

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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 Frederick County 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 strict liability for specified damages if the laboratory fails 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.

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**Fiscal Summary**

**State Effect:** MDH can develop a strategy to identify and notify affected BSL-3 laboratories, develop the standardized form and collect required information, and fulfill the bill’s reporting requirements with existing budgeted staff and resources. Any affected State-run BSL-3 laboratory can comply with the reporting requirements with existing budgeted resources.

**Local Effect:** Assuming any local government-run BSL-3 laboratory in Frederick County complies with the bill’s reporting requirements, the bill is not expected to materially affect local operations or finances.

**Small Business Effect:** Minimal; assuming any affected BSL-3 laboratory in Frederick County that is a small business or is owned by a small business complies with the bill’s reporting requirements.

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## 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 National Institutes of Health (NIH)’s *Biosafety in Microbiological and Biomedical Laboratories*, 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. The bill only applies to a BSL-3 laboratory in Frederick County.

Annually by October 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 of BSL-3 laboratories in Frederick County to the Maryland Emergency Management Agency and the health officer and emergency management officials of Frederick County and (2) the total number of BSL-3 laboratories in Frederick County 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. However, any information collected must be made available, if requested, by a BSL-3 laboratory’s insurance carrier or in a legal proceeding.

If a BSL-3 laboratory fails to report required information, that laboratory’s activity is considered ultrahazardous and abnormally dangerous, and the laboratory is strictly liable for damages for any injury, death, or loss to person or property that is caused by the laboratory.

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, CDC and NIH 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, *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.

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### **Additional Information**

**Prior Introductions:** SB 187 of 2019, a similar bill with statewide application, received a hearing in the Senate Finance Committee, but no further action was taken. Its cross file, HB 383, received a hearing in the House Health and Government Operations Committee, but no further action was taken. SB 392 of 2018, a similar bill with statewide application, received a hearing in the Senate Finance Committee, but no further action was taken. Its cross file, HB 655, passed the House and received a hearing in the Senate Finance Committee, but no further action was taken. Similar bills with statewide application were also introduced in the 2017 and 2016 sessions.

**Designated Cross File:** SB 450 (Senators Young and Hough) - Finance.

**Information Source(s):** University System of Maryland; Maryland Department of Agriculture; Maryland Department of Health; Department of State Police; Military Department; Department of Legislative Services

**Fiscal Note History:** First Reader - February 11, 2020  
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