

**Department of Legislative Services**  
 Maryland General Assembly  
 2002 Session

**FISCAL NOTE**  
**Revised**

House Bill 361

(Delegate Hubbard)

Environmental Matters

Education, Health, and Environmental Affairs

**Department of Health and Mental Hygiene - Biological Agents Registry Program**

This bill establishes a Biological Agents Registry Program within the Department of Health and Mental Hygiene (DHMH).

**Fiscal Summary**

**State Effect:** General fund expenditures would increase by \$95,000 in FY 2003 to staff the program. Future years reflect annualization and inflation. Revenues would not be affected.

(in dollars)	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
Revenues	\$0	\$0	\$0	\$0	\$0
GF Expenditure	95,000	108,700	113,500	118,500	123,900
Net Effect	(\$95,000)	(\$108,700)	(\$113,500)	(\$118,500)	(\$123,900)

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

**Local Effect:** Potential minimal. Local entities working with select biological agents would be required to report data under the program unless they are exempt under federal regulations.

**Small Business Effect:** Potential minimal. Small businesses working with select biological agents would be required to report data under the program unless they are exempt under federal regulations.

## **Analysis**

**Bill Summary:** The Biological Agents Registry must identify specified “biological agents” possessed and maintained by any person in the State and contain other information as required by regulations adopted by DHMH.

DHMH must adopt regulations to implement the program that:

- determine and list biological agents;
- designate the people required to report on biological agents and the information to be included in the report;
- designate time limits for reporting information, the report forms, and the persons to whom reports are submitted;
- provide for releasing information to State and federal law enforcement agencies and the Centers for Disease Control and Prevention in response to a communicable disease investigation or in connection with any investigation of release, theft, or loss of biological agents;
- establish a system of safeguards that requires people possessing, maintaining, and transferring biological agents to comply with the same federal standards that apply to people registered to transfer the same agents under federal law; and
- establish a process for people that possess and maintain biological agents to alert authorities of unauthorized possession or attempted possession of biological agents.

This bill does not apply to a biological agent or certified laboratory or facility exempt from the requirements applicable to the federal interstate shipment of etiologic agents.

Information prepared for or maintained in the biological agents registry is confidential and not subject to the Access to Public Records Law.

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

**Current Law:** Drug manufacturers, distributors, and dispensers must register with the Board of Pharmacy to dispense controlled dangerous substances. Dispensers include licensed pharmacists and licensed health care practitioners such as physicians, dentists, veterinarians, or other health care practitioners authorized to prescribe controlled dangerous substances within the scope of their practice. All registrants must maintain

inventory records of controlled dangerous substances. In addition, registrants must provide effective controls and procedures to guard against theft and unlawful diversion of controlled substances. In the case of theft or loss of controlled dangerous substances, registrants must notify the regional office of the Drug Enforcement Administration and DHMH's Division of Drug Control upon discovery of the loss or theft.

Generally, a custodian of a public record must permit inspection of the record at a reasonable time.

A custodian must deny inspection of a public record or any part of a public record if: (1) the public record is privileged or confidential by law; or (2) the inspection would be contrary to: (a) a State statute; (b) a federal statute or regulation; (c) the Maryland Rules; or (d) an order of a court record. Denial of inspection is also mandatory for public records relating to adoption, welfare records, letters of reference, and specified information about an individual maintained by a library. Denial of inspection is permissible for information in a public record relating to certain medical, psychological, sociological information; trade secrets; certain personal information about public employees; information about the security of an information system; and licensing records.

The federal Department of Health and Human Services (HHS) generally requires a facility, before transferring or receiving select biological agents, to register with an HHS-authorized entity or be approved by HHS to handle the select agents. A facility is exempt from this requirement if the agent is part of a specimen for diagnostic, reference, or verification purposes or is an exempted strain. A facility is also exempt if the agent is a toxin being used for medical purposes, biomedical research, or has been inactivated and used as a vaccine or for research. Clinical laboratories certified under the federal Clinical Laboratory Improvements of 1988 also are exempted.

**Background:** The federal government operates a biological agents registry program. However, the program does not have the capability of auditing facilities reporting information nor does it keep track of the amount of biological agents at the facilities.

**State Expenditures:** General fund expenditures could increase by an estimated \$94,973 in fiscal 2003 which accounts for the bill's October 1, 2002 effective date. This estimate reflects the cost of hiring a laboratory scientist to design and implement a system to report possession of biological agents and an office secretary to provide administrative support. It includes salaries, fringe benefits, one-time start-up costs, travel, and ongoing operating expenses.

Salaries and Fringe Benefits	\$72,819
Operating Expenses	<u>22,154</u>
<b>Total FY 2003 State Expenditures</b>	<b>\$94,973</b>

Future year expenditures reflect: (1) full salaries with 3.5% annual increases and 3% employee turnover; and (2) 1% annual increases in ongoing operating expenses.

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### **Additional Information**

**Prior Introductions:** None.

**Cross File:** None.

**Information Source(s):** Department of Health and Mental Hygiene, Department of Legislative Services

**Fiscal Note History:** First Reader - February 8, 2002  
ncs/jr Revised - House Third Reader - April 1, 2002  
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