

COMMITTEE ON LEGISLATIVE RESEARCH  
OVERSIGHT DIVISION

**FISCAL NOTE**

L.R. No.: 1553H.01I  
 Bill No.: HB 995  
 Subject: Health, Public; Health and Senior Services, Department of  
 Type: Original  
 Date: February 19, 2021

Bill Summary: This proposal modifies provisions relating to medical confidentiality.

**FISCAL SUMMARY**

<b>ESTIMATED NET EFFECT ON GENERAL REVENUE FUND</b>			
FUND AFFECTED	FY 2022	FY 2023	FY 2024
General Revenue	(Unknown, greater than \$333,333)	(Unknown, greater than \$341,666)	(Unknown, greater than \$350,209)
<b>Total Estimated Net Effect on General Revenue</b>	<b>(Unknown, greater than \$333,333)</b>	<b>(Unknown, greater than \$341,666)</b>	<b>(Unknown, greater than \$350,209)</b>

<b>ESTIMATED NET EFFECT ON OTHER STATE FUNDS</b>			
FUND AFFECTED	FY 2022	FY 2023	FY 2024
MOPHS	(Unknown, greater than \$108,333)	(Unknown, greater than \$34,166)	(Unknown, greater than \$35,020)
<b>Total Estimated Net Effect on <u>Other</u> State Funds</b>	<b>(Unknown, greater than \$108,333)</b>	<b>(Unknown, greater than \$34,166)</b>	<b>(Unknown, greater than \$35,020)</b>

Numbers within parentheses: () indicate costs or losses.

<b>ESTIMATED NET EFFECT ON FEDERAL FUNDS</b>			
<b>FUND AFFECTED</b>	<b>FY 2022</b>	<b>FY 2023</b>	<b>FY 2024</b>
Federal*	\$0	\$0	\$0
<b>Total Estimated Net Effect on <u>All</u> Federal Funds</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>

\*Income and expenses Unknown, greater than \$34,000 annually and net to \$0

<b>ESTIMATED NET EFFECT ON FULL TIME EQUIVALENT (FTE)</b>			
<b>FUND AFFECTED</b>	<b>FY 2022</b>	<b>FY 2023</b>	<b>FY 2024</b>
General Revenue	Unknown FTE	Unknown FTE	Unknown FTE
MOHPS	Unknown FTE	Unknown FTE	Unknown FTE
Federal	Unknown FTE	Unknown FTE	Unknown FTE
<b>Total Estimated Net Effect on FTE</b>	<b>Unknown FTE</b>	<b>Unknown FTE</b>	<b>Unknown FTE</b>

Estimated Net Effect (expenditures or reduced revenues) expected to exceed \$250,000 in any of the three fiscal years after implementation of the act or at full implementation of the act.

Estimated Net Effect (savings or increased revenues) expected to exceed \$250,000 in any of the three fiscal years after implementation of the act or at full implementation of the act.

FORMCHECKBOX

<b>ESTIMATED NET EFFECT ON LOCAL FUNDS</b>			
<b>FUND AFFECTED</b>	<b>FY 2022</b>	<b>FY 2023</b>	<b>FY 2024</b>
<b>Local Government</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>

## FISCAL ANALYSIS

### ASSUMPTION

#### §§191.241, 191.317, and 375.1309 – Medical confidentiality

Officials from the **Department of Health and Senior Services (DHSS)** state House Bill 995 requires all persons to be informed at the time of collection of any biological specimen of their right to give direction to laboratories that the biological specimen will not be released for purposes of anonymous scientific study. This bill also states that any person from which a biological specimen is collected has the right to have that biological specimen returned to them or stored at the laboratory for up to five years.

This legislation does not define “anonymous scientific study”. The DHSS, State Public Health Laboratory (SPHL), conservatively assumes that the definition is any use beyond the test that it was submitted for. With this assumption, this legislation will impact the quality of laboratory testing by the inability to use biological specimens for internal quality control for method development and quality checks for rare diseases or disorders in which commercial outlets are unavailable. This will also disrupt development of new technologies to test for disorders and novel pathogens such as SARS-CoV-2, Ebola, newborn disorders, etc. due to the unavailability of biological specimens for test development.

In addition, Missouri’s newborn screening program, which screens approximately 75,000 newborns in Missouri for over 73 various metabolic and genetic disorders, will no longer have the ability to assure new testing capabilities, quality of existing screening, and demonstration of proficiency.

#### §191.241.3(1)

A biological specimen is a biohazard and can contain blood borne pathogens. Various shipping regulations and laws prohibit the shipping of biological specimens that contain known pathogens and are not allowed by federal regulation to be shipped via United States Postal Service; therefore, the specimens will be shipped FedEx or UPS for an annual unknown fiscal impact greater than \$100,000.

#### §§191.241.3 and 191.317

Additional staff will be required manage and process the individual biological specimen requests, storing and tracking specimens, shipping specimens back to patients, and destroying specimens as requested. With no way of determining the number of each of these requests, there is an unknown fiscal impact greater than \$100,000 for personal service. Personal service costs could come from General Revenue (GR), the MO Public Health Services (MOPHS) Fund, Federal funds, or a combination of the three. For fiscal impact response purposes, an unknown annual personal service cost of greater than \$33,333 will be added to each funding source.

The SPHL will require additional space equipped with cooling units to hold the biological specimens that are requested for five-year storage. Currently, the SPHL receives hundreds of thousands of biological specimens each year; there is no way to estimate the number of requests that will be made to store the specimens; therefore, there is an unknown annual fiscal impact greater than \$100,000 for additional storage space and cooling units.

SPHL will be required to modify and implement changes in the current contracted laboratory information systems to record, track and manage the status and inventory of incoming and stored biological specimens for an unknown fiscal impact greater than \$100,000.

§191.317.2

SPHL will be required to produce updated newborn screening collection kits to comply with the requirements of the legislation for an estimated one-time cost of \$75,000 (MOPHS).

**Oversight** has no information to the contrary and will present DHSS estimated costs as provided.

§375.1309 – Penalty provisions

Officials from the **Department of Corrections (DOC)** state this proposal intends to improve the confidentiality and consent requirements related to collection, returning, destroying, testing and using biological specimen for anonymous scientific studies.

Under §375.1309 subsection 2, the penalty for violating this section has been increased from a level two violation under §374.049 to a class A felony.

As per §374.049, the penalty for level two violation is *One thousand dollars per each level two violation, up to an aggregate civil penalty or forfeiture of fifty thousand dollars per annum for multiple violations.*

Since level two violations are not reported to DOC, the DOC does not have sufficient data to determine the frequency of the offense. Thus, it is not possible to gauge what population may be impacted by the increase in penalty from a level two violation to a class A felony. The result may range from insignificant impact to the maximum extent of a new class A felony. Therefore, the DOC assumes a \$0 to (Unknown) fiscal impact to the General Revenue Fund.

**Oversight** contacted Department of Commerce and Insurance (DCI) officials as Chapter 374 deals with business and financial institutions. DCI officials indicated that any penalties collected under §374.049 would be distributed to schools. They do not have any information available on whether any level two violations have been issued, or penalties collected, in recent years. Since Oversight has no information available regarding the possible number of level two violations, it is assumed there would not be a significant number of individuals violating these provisions. Therefore, Oversight assumes no fiscal impact to the DOC for fiscal note purposes.

Responses regarding the proposed legislation as a whole

Officials from the **Department of Public Safety – Missouri Highway Patrol**, the **Missouri Office of Prosecution Services**, the **Office of the State Courts Administrator**, the **Office of the State Public Defender**, the **Columbia/Boone County Department of Public Health and Human Services**, the **Kansas City Health Department**, the **Newton County Health Department**, the **St. Louis County Health Department** and the **Hermann Area Hospital District** each assume the proposal will have no fiscal impact on their respective organizations. **Oversight** does not have any information to the contrary. Therefore, Oversight will reflect a zero impact in the fiscal note for these agencies.

**Oversight** only reflects the responses that we have received from state agencies and political subdivisions; however, other local public health agencies and hospitals were requested to respond to this proposed legislation but did not. A general listing of political subdivisions included in our database is available upon request.

This proposal has an emergency clause.

<u>FISCAL IMPACT – State Government</u>	FY 2022	FY 2023	FY 2024
<b>GENERAL REVENUE FUND</b>			
<u>Costs – DHSS</u> (§§191.241 and 191.317)			
Personal services	(Unknown, greater than \$33,333)	(Unknown, greater than \$34,166)	(Unknown, greater than \$35,020)
Fringe benefits	(Unknown)	(Unknown)	(Unknown)
Equipment and expense	(Unknown, greater than \$200,000)	(Unknown, greater than \$205,000)	(Unknown, greater than \$210,126)
Information system development	(Unknown, greater than \$100,000)	(Unknown, greater than \$102,500)	(Unknown, greater than \$105,063)
<u>Total Costs - DHSS</u>	<u>(Unknown, greater than \$333,333)</u>	<u>(Unknown, greater than \$341,666)</u>	<u>(Unknown, greater than \$350,209)</u>
FTE Change – DHSS	Unknown FTE	Unknown FTE	Unknown FTE
<b>ESTIMATED NET EFFECT ON THE GENERAL REVENUE FUND</b>	<b><u>(Unknown, greater than \$333,333)</u></b>	<b><u>(Unknown, greater than \$341,666)</u></b>	<b><u>(Unknown, greater than \$350,209)</u></b>
Estimated Net FTE Change on the General Revenue Fund	Unknown FTE	Unknown FTE	Unknown FTE

<u>FISCAL IMPACT – State Government (continued)</u>	FY 2022	FY 2023	FY 2024
<b>MOPHS FUND (0298)</b>			
<u>Costs – DHSS</u> (§§191.241 and 191.317)			
Personal services	(Unknown, greater than \$33,333)	(Unknown, greater than \$34,166)	(Unknown, greater than \$35,020)
Fringe benefits	(Unknown)	(Unknown)	(Unknown)
Newborn screen collection kits	<u>(\$75,000)</u>	<u>\$0</u>	<u>\$0</u>
<u>Total Costs - DHSS</u>	<u>(Unknown, greater than \$108,333)</u>	<u>(Unknown, greater than \$34,166)</u>	<u>(Unknown, greater than \$35,020)</u>
FTE Change – DHSS	Unknown FTE	Unknown FTE	Unknown FTE
<b>ESTIMATED NET EFFECT ON THE MOPHS FUND</b>	<b><u>(Unknown, greater than \$108,333)</u></b>	<b><u>(Unknown, greater than \$34,166)</u></b>	<b><u>(Unknown, greater than \$35,020)</u></b>
Estimated Net FTE Change on the MOPHS Fund	Unknown FTE	Unknown FTE	Unknown FTE

<u>FISCAL IMPACT – State Government</u> (continued)	FY 2022	FY 2023	FY 2024
<b>FEDERAL FUNDS</b>			
<u>Income – DHSS</u> (§§191.241 and 191.317)			
Reimbursement for program costs	Unknown, greater than \$33,333	Unknown, greater than \$34,166	Unknown, greater than \$35,020
<u>Costs – DHSS</u> (§§191.241 and 191.317)			
Personal services	(Unknown, greater than \$33,333)	(Unknown, greater than \$34,166)	(Unknown, greater than \$35,020)
Fringe benefits	(Unknown)	(Unknown)	(Unknown)
<u>Total Costs - DHSS</u>	<u>(Unknown, greater than \$33,333)</u>	<u>(Unknown, greater than \$34,166)</u>	<u>(Unknown, greater than \$35,020)</u>
FTE Change – DHSS	Unknown FTE	Unknown FTE	Unknown FTE
<b>ESTIMATED NET EFFECT ON FEDERAL FUNDS</b>	<b><u>\$0</u></b>	<b><u>\$0</u></b>	<b><u>\$0</u></b>
Estimated Net FTE Change on Federal Funds	Unknown FTE	Unknown FTE	Unknown FTE

<u>FISCAL IMPACT – Local Government</u>	FY 2022	FY 2023	FY 2024
	<b><u>\$0</u></b>	<b><u>\$0</u></b>	<b><u>\$0</u></b>

FISCAL IMPACT – Small Business

This proposal may have a negative fiscal impact on small business laboratories. (§191.241)

FISCAL DESCRIPTION

The bill establishes criteria for what a laboratory is able to do with any biological specimen collected or received by a laboratory from an individual. A biological specimen shall not be released for purposes of anonymous scientific study unless the individual or the parent or legal guardian for an individual who is a child consents to such release. An individual or their guardian, at the time of collection, can direct the laboratory to return the specimen after testing has been performed, destroy the specimen or store the specimen. The laboratory must obtain consent to release the specimen for anonymous scientific study from the individual or guardian for any specimen collected prior to the effective date of this bill, unless consent was given at the time of collection.

These provisions shall not apply to biological specimens subject to the requirements of §375.1309, RSMo, or biological specimens obtained from infants for testing of metabolic and genetic diseases in accordance with §191.331 that are subject to the confidentiality requirements of §191.317. (§§191.241, 191.317, and 375.1309)

A violation of this provisions in a class A felony.

This bill contains an emergency clause.

This legislation is not federally mandated, would not duplicate any other program but may require additional capital improvements or rental space.

SOURCES OF INFORMATION

Department of Health and Senior Services  
Department of Corrections  
Department of Public Safety –  
    Missouri Highway Patrol  
Missouri Office of Prosecution Services  
Office of the State Courts Administrator  
Office of the State Public Defender  
Columbia/Boone County Department of Public Health and Human Services  
Kansas City Health Department  
Newton County Health Department  
St. Louis County Health Department  
Hermann Area Hospital District



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