

LEGISLATIVE FISCAL ESTIMATE

[First Reprint]

SENATE, No. 3975

STATE OF NEW JERSEY
219th LEGISLATURE

DATED: NOVEMBER 26, 2021

SUMMARY

- Synopsis:

Establishes requirements to commence screening newborn infants for congenital cytomegalovirus infection; establishes public awareness campaign.
- Type of Impact:

Potential annual State expenditure and revenue increases starting in a fiscal year to be determined; potential annual expenditure increases to University Hospital
- Agencies Affected:

Department of Health, University Hospital

Office of Legislative Services Estimate

Fiscal Impact	<u>FY 2022-FY 2023</u>	<u>FY 2024 & Thereafter</u>
State Cost Increase	No Impact	No Impact or Indeterminate
State Revenue Increase	No Impact	No Impact or Indeterminate
University Hospital-Cost Increase	No Impact	No Impact or Indeterminate

- The Office of Legislative Services (OLS) concludes that there will be no fiscal impact on the State related to the screening of newborn infants for congenital cytomegalovirus (cCMV) until the criteria set forth in the bill for the testing of infants are met. It does not appear that the criteria will be satisfied for several years.
- Annual State costs may increase when the cCMV test is implemented, but these costs cannot be determined without knowledge of what such a test would entail. The revenue generated by the fee charged to hospitals by the Department of Health (DOH) to perform the tests may or may not offset these additional State costs.
- To the extent that hospital fees are imposed under the bill for the performance of the cCMV test, University Hospital, an independent non-profit legal entity that is an instrumentality of the State located in Newark, will experience an indeterminate increase in annual expenditures.

- The DOH may incur marginal costs upon enactment of the bill to establish a public awareness campaign regarding the cytomegalovirus and cCMV; however, it is likely that this expense could be absorbed by the department's existing operating budget using current staff.

BILL DESCRIPTION

This bill requires that all infants born in the State be tested for cCMV six months after the following occurs:

(1) the development of a reliable test or series of tests for screening newborns for cCMV using dried blood spots and quality assurance testing methodology for cCMV testing;

(2) the availability of quality assurance materials for the test from the federal Centers for Disease Control and Prevention;

(3) the inclusion of newborn screening for cCMV in the Recommended Uniform Screening Panel of the United States Secretary of Health and Human Services' Advisory Committee on Heritable Disorders in Newborns and Children, after the committee's evidence review of newborn screening for cCMV;

(4) the recommendation by the State's Newborn Screening Advisory Review Committee that the test be included in the Newborn Screening Program;

(5) the Commissioner of Health's approval to include the test in the State's Newborn Screening Program; and

(6) the acquisition of equipment necessary to implement the expanded screening tests by the State's Newborn Screening Laboratory.

The DOH may charge a reasonable fee for the test and may periodically increase the fee by a reasonable amount as the department deems necessary.

The department is to establish a public awareness campaign to educate pregnant persons about cytomegalovirus and cCMV, develop outreach efforts, and provide relevant educational materials to pregnant persons.

FISCAL ANALYSIS

EXECUTIVE BRANCH

None received.

OFFICE OF LEGISLATIVE SERVICES

The OLS concludes that there will be no fiscal impact on the State related to the screening of newborn infants for cCMV until the criteria set forth in the bill for the testing of infants are met. It does not appear that the criteria will be satisfied for several years.

For example, the first criterion for implementation of the bill is the development of a reliable test or series of tests for screening newborns for cCMV using dried blood spots. While recent studies performed at the University of Minnesota Medical School demonstrated that a dried blood spot taken at birth can detect a cCMV infection in a newborn with almost 90 percent accuracy, the United States Food and Drug Administration has currently only approved the marketing of a test that detects cCMV from a saliva swab.

Another criterion before screenings are implemented requires the inclusion of newborn screening for cCMV in the federal Recommended Uniform Screening Panel. In 2018, the National

CMV Foundation submitted a nomination package to the federal government for such an inclusion. Upon the request for additional data to support the nomination package, the National CMV Foundation decided to delay, at least temporarily, the pursuit of the nomination. There is currently no nomination package pending for the inclusion of cCMV testing in the Recommended Uniform Screening Panel.

Even if all other criteria are met, inclusion of the cCMV test in the Newborn Screening Program is dependent on the DOH acquiring the necessary equipment to implement the expanded screening, which the department is not required to do. Furthermore, current law provides the Commissioner of Health with the authority to add additional tests to the Newborn Screening Program or not.

If a test for cCMV is added to the Newborn Screening Program, annual State expenditures may increase, but these costs cannot be determined without knowledge of what such a test would entail. Currently, the Newborn Screening Program screens approximately 100,000 children born in New Jersey each year for a panel of 59 disorders. The current fee under the Newborn Screening Program is \$150, which the DOH levies on hospitals in order to perform the test. If the test can be conducted using the same blood sample that is used for other newborn screening tests, it is likely that additional costs would be nominal. Any additional costs to the State may or may not be offset by the revenue generated from the fee the department is authorized to charge to perform the test. To the extent that hospital fees are imposed under the bill for the performance of the cCMV test, University Hospital, an independent non-profit legal entity that is an instrumentality of the State located in Newark, will experience an indeterminate increase in annual expenditures.

The DOH may incur marginal costs upon enactment of the bill to establish a public awareness campaign regarding the cytomegalovirus and cCMV; however, it is likely that this expense could be absorbed by the department's existing operating budget using current staff as educating the public about the symptoms and treatment of health conditions is a component of the department's mission and the provisions of the bill do not require the campaign to include any printed material.

Section: *Human Services*
Analyst: *Sarah Schmidt*
 Senior Research Analyst II
Approved: *Thomas Koenig*
 Legislative Budget and Finance Officer

This legislative fiscal estimate has been produced by the Office of Legislative Services due to the failure of the Executive Branch to respond to our request for a fiscal note.

This fiscal estimate has been prepared pursuant to P.L.1980, c.67 (C.52:13B-6 et seq.).