

## Department of Planning and Budget

### 2019 Fiscal Impact Statement

**1. Bill Number:** HB2026

**House of Origin**    ☐ Introduced    ☐ Substitute    ☐ Engrossed  
**Second House**    ☐ In Committee    ☐ Substitute    ☒ Enrolled

**2. Patron:** Stolle

**3. Committee:** Passed both Houses.

**4. Title:** Newborn screening; congenital cytomegalovirus.

**5. Summary:** Directs the Board of Health to amend regulations governing newborn screening to include screening for congenital cytomegalovirus in newborns who fail the newborn hearing screen.

**6. Budget Amendment Necessary:** See item #8.

**7. Fiscal Impact Estimates:** See item #8.

**7a. Expenditure Impact:**

<i>Fiscal Year</i>	<i>Dollars</i>	<i>Positions</i>	<i>Fund</i>
2019			
2020	\$60,000	0	Nongeneral
2020	\$198,589	0.5	General
2021	\$138,638	1	Nongeneral
2021	\$35,500	0.5	General
2022	\$138,638	1	Nongeneral
2022	\$35,500	0.5	General
2023	\$138,638	1	Nongeneral
2023	\$35,500	0.5	General
2024	\$138,638	1	Nongeneral
2024	\$35,500	0.5	General
2025	\$138,638	1	Nongeneral
2025	\$35,500	0.5	General

**7b. Revenue Impact:**

<i>Fiscal Year</i>	<i>Dollars</i>	<i>Fund</i>
2019	0	
2020	0	Nongeneral
2021	\$138,638	Nongeneral
2022	\$138,638	Nongeneral
2023	\$138,638	Nongeneral
2024	\$138,638	Nongeneral
2025	\$138,638	Nongeneral

**8. Fiscal Implications:** This bill would have a fiscal impact on the commonwealth.

**Virginia Department of Health:** The Office of Information Management has estimated that enhancements to the Virginia Infant Screening and Tracking System (VISITS) to capture congenital cytomegalovirus (CMV) data would be \$164,589 with annual maintenance costs of \$1,500. According to § 32.1-68 of the Code, the screening program shall include provisions for education, post-screening counseling, and laboratory testing. The department estimates that a wage position at a rate of \$29,000 per year would be required to implement the program, educate and train stakeholders about CMV, assist in VISITS enhancements requirements, monitor and document CMV infants and their outcomes and report findings. Furthermore, an education campaign to include CMV information on print materials, website updates, and when traveling to relevant national conferences would cost an estimated \$5,000 per year.

**Department of General Services:** The Division of Consolidated Laboratory Services will need to implement a new fee for the required testing of CMV. DCLS does not currently offer CMV testing and would require appropriation to both implement and sustain the testing in support of the VDH/Early Hearing Detection and Intervention (EHDI) Program. Based on DCLS' preliminary analysis, this testing is estimated to cost \$37 per test for reagents and consumables. DCLS would require a minimum of 12 months to stand up, validate and implement this testing and as a result it is assumed that no revenue from testing services will be realized until 2021. There is a first year implementation cost of \$60,000 for Lab Information Management System (LIMS) development and hardware. There is currently only one FDA-approved newborn CMV testing kit available for purchase. The price quote for the testing kit was based on an annual sample volume of 1625 samples/year; and the instrumentation needed for this testing is provided by the vendor through the purchase of reagent kits. Annual costs assume an estimate of 1625 samples per year with a 10 percent in-lab repeat rate and running the testing Monday – Friday. In order to address the increase in workload, two wage positions will be needed at a rate of \$36,250 per position.

**Department of Medical Assistance Services:** If commercial laboratories were utilized for CMV screening, there would be a fiscal impact on the Department of Medical Assistance Services (DMAS) and managed care organizations (MCOs). Comments from this agency are pending.

**9. Specific Agency or Political Subdivisions Affected:** The Virginia Department of Health and the Department of General Services.

**10. Technical Amendment Necessary:** No.

**11. Other Comments:** None.