

SENATE BILL REPORT

SB 5829

As Reported by Senate Committee On:
Health & Long Term Care, January 25, 2024

Title: An act relating to screening newborn infants for congenital cytomegalovirus.

Brief Description: Screening newborn infants for congenital cytomegalovirus.

Sponsors: Senators Frame, Rivers, Shewmake, Trudeau, Lovelett, Dhingra, Hasegawa, Kuderer, Lias, Nobles, Valdez and Wilson, C..

Brief History:

Committee Activity: Health & Long Term Care: 1/12/24, 1/25/24 [DPS].

Brief Summary of First Substitute Bill

- Directs the State Board of Health to consider adding Congenital Cytomegalovirus screening to the mandatory screening panel and submit a report with the findings and recommendations by December 31, 2025.

SENATE COMMITTEE ON HEALTH & LONG TERM CARE

Majority Report: That Substitute Senate Bill No. 5829 be substituted therefor, and the substitute bill do pass.

Signed by Senators Cleveland, Chair; Robinson, Vice Chair; Rivers, Ranking Member; Muzzall, Assistant Ranking Member; Conway, Dhingra, Holy, Padden, Randall and Van De Wege.

Staff: Julie Tran (786-7283)

Background: Congenital Cytomegalovirus. Congenital Cytomegalovirus (cCMV) is a common congenital infection and is present in approximately 1 in 200 babies. cCMV occurs when a pregnant individual is infected with cytomegalovirus and subsequently passes the infection to their unborn child. It can result in hearing loss and is the leading cause of

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nonhereditary, sensorineural hearing loss.

Washington State's Newborn Screenings. Department of Health (DOH) must require screening tests of all newborn infants born in any setting. No tests shall be given to any newborn infant whose parents or guardian object on the grounds of religious tenets and practices.

Each hospital or health care provider attending a birth outside of a hospital must collect and submit a sample blood specimens for all newborn infants within 48 hours following the birth. The initial screen or signed refusal must be delivered to the state laboratory within 72 hours of collection, excluding Sundays and Thanksgiving Day. Laboratories, attending physicians, hospital administrators or other persons are required to report all positive test results to DOH.

Annually, DOH performs nearly 12 million tests on more than 172,000 specimens from about 85,000 newborn infants. DOH also provides information and training to parents and health care providers about newborn screenings (NBS).

Newborn Screening Panel. Washington State adds tests to the newborn screening panel only after a consideration of the following criteria set by the State Board of Health (Board): available technology, diagnostic testing, and treatment available; prevention potential and medical rationale; public health rationale; cost-benefit and cost-effectiveness.

In October 2021, the Board convened a technical advisory committee to consider adding cCMV to the list of mandated NBS conditions. In October 2022, the Board determined cCMV should not be considered for addition to the newborn screening panel at this time and moves to reevaluate the condition in three years as a candidate for mandatory newborn screening in Washington State.

In Washington, there are no state requirements for cCMV education, screening, or reporting. Cytomegalovirus testing is up to a provider's discretion and results are not reported to DOH.

Summary of Bill (First Substitute): The Board is required to consider whether or not to add cCMV screening to the mandatory newborn screening panel and submit legislature a report no later than December 31, 2025 to the Governor and Legislature. The report must include a summary of the conducted evaluation and the findings and recommendations on the addition of cCMV screening to the mandatory newborn screening panel.

DOH is required to develop and make available educational resources for pregnant individuals about the nature and consequences of in utero exposure to CMV and strategies to reduce the CMV transmission. The educational resources may include, but are not limited to, courses delivered in-person or electronically, pamphlets printed on paper and distributed through the watch me grow program, social media content, or made available on DOH's

website. DOH is also required to provide educational materials and outreach for providers regarding the strategies to reduce CMV transmission. The educational materials are intended to lower CMV infection rates among pregnant individuals to save lives and prevent disability in their unborn children.

EFFECT OF CHANGES MADE BY HEALTH & LONG TERM CARE COMMITTEE (First Substitute):

- Removes the opt-in screening option for cCMV and the provisions related to the opt-in screening and directs the Board to consider adding cCMV screening to the mandatory screening panel and submit a report with the findings and recommendations by December 31, 2025.
- Directs DOH to develop and make available educational resources for pregnant individuals about the nature and consequences of in-utero exposure to CMV and strategies to reduce CMV transmission and specifies what type of educational resources may be included.
- Requires DOH to provide educational materials and outreach for providers about the strategies to reduce CMV transmission.
- Removes the provision directing DOH to design, prepare, and make available written material to inform health care providers and parents or guardians of newborn infants about the nature and consequences of cCMV.

Appropriation: The bill contains a section or sections to limit implementation to the availability of amounts appropriated for that specific purpose.

Fiscal Note: Available.

Creates Committee/Commission/Task Force that includes Legislative members: No.

Effective Date: Ninety days after adjournment of session in which bill is passed.

Staff Summary of Public Testimony on Original Bill: *The committee recommended a different version of the bill than what was heard.* PRO: CMV is the leading viral cause of birth defects and developmental delays in children as well as other condition such as seizures, hearing loss, cerebral palsy, brain abnormalities, autism, and sadly, death. CMV is easily preventable and most babies with cCMV never show any signs of health problems. The bill does two things: education upfront so parents understand and take the necessary precautions and an opt-in newborn screening for the condition. This bill includes DOH guidance to have an opt-in screening using the existing blood sample that DOH already has and prioritizes the use of existing tests, so that CMV was the last test in case the blood sample did not go as far. This condition causes more birth defects than other well-known disorders and syndrome, more than any other disorder currently tested for in the Washington State newborn screening panel. Early treatment and intervention is paramount. There are antiviral medication that can improve outcomes but newborn infants must be

screened in the first 2-3 weeks of birth to receive the medication. The antiviral medication can minimize outcomes and improve many children's lives. This bill allows Washington to have a formal screening protocol and allows families an opportunity to have their infant screened for CCMV. The state should advocate for newborns and families by giving them the option to take a quick and education action at birth.

CON: cCMV is a serious condition and a public health problem of great consequence. The board and the department recently reviewed cCMV for inclusion in the state's NBS panel and found that screening babies through a bloodspot specimen is not the most effective way to prevent death and disability from the condition. Early identification and treatment through NBS will not prevent severe death and disability from cCMV. Current antiviral therapy has not been shown to prevent death for babies with symptomatic CMV infection. The current test on dried blood specimens is only 75 percent sensitive and there are concerns about offering a test that will miss 25 percent of the babies with CMV. Screening using other tests such as saliva testing has a higher sensitivity but the Board and DOH do not have the authority or capacity to conduct these tests. There also may not be sufficient audiologists to handle the increased follow-up diagnostic testing for babies identified with this condition. Implementing the necessary screening and follow-up will require significant funding, and it was not included in the Governor's budget. The board has committed to reevaluating the condition next year in 2025 and ask for the ability to follow their process for considering candidate conditions. The way to save lives is to prevent transmission of CMV from pregnant individuals, which is through education instead of optional screening.

Persons Testifying: PRO: Senator Noel Frame, Prime Sponsor; Mallory Baker, Washington CMV Project; Cathleen Ackley; Lisa Aamot; Kelsey Gellner, WSNA.

CON: John Thompson, Washington State Department of Health; Molly Dinardo, Washington State Board of Health.

Persons Signed In To Testify But Not Testifying: No one.