PETITION FOR ADOPTION, AMENDMENT, OR REPEAL OF A STATE ADMINISTRATIVE RULE

Print Form

In accordance with RCW 34.05.330, the Office of Financial Management (OFM) created this form for individuals or groups who wish to petition a state agency or institution of higher education to adopt, amend, or repeal an administrative rule. You may use this form to submit your request. You also may contact agencies using other formats, such as a letter or email.

The agency or institution will give full consideration to your petition and will respond to you within 60 days of receiving your petition. For more information on the rule petition process, see Chapter 82-05 of the Washington Administrative Code (WAC) at http://apps.leg.wa.gov/wac/default.aspx?cite=82-05.

CONTACT INFORMATION *(please type or print)*

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COMPLETING AND SENDING PETITION FORM

- Check all of the boxes that apply.
- Provide relevant examples.
- Include suggested language for a rule, if possible.
- Attach additional pages, if needed.
- Send your petition to the agency with authority to adopt or administer the rule. Here is a list of agencies and their rules coordinators: http://www.leg.wa.gov/CodeReviser/Documents/RClist.htm.

INFORMATION ON RULE PETITION

Agency responsible for adopting or administering the rule: Department of Health

☒ **1. NEW RULE - I am requesting the agency to adopt a new rule.**

☒ The subject (or purpose) of this rule is: See attached

☒ The rule is needed because: See attached

☒ The new rule would affect the following people or groups: See attached

☐ **2. AMEND RULE - I am requesting the agency to change an existing rule.**

List rule number (WAC), if known: _____

☐ I am requesting the following change: _____

☐ This change is needed because: _____

☐ The effect of this rule change will be: _____

☐ The rule is not clearly or simply stated: _____

☐ **3. REPEAL RULE - I am requesting the agency to eliminate an existing rule.**

List rule number (WAC), if known: _____

(Check one or more boxes)

☐ It does not do what it was intended to do.

☐ It is no longer needed because: _____

☐ It imposes unreasonable costs: _____

☐ The agency has no authority to make this rule: _____

☐ It is applied differently to public and private parties: _____

☐ It conflicts with another federal, state, or local law or rule. List conflicting law or rule, if known: _____

☐ It duplicates another federal, state or local law or rule. List duplicate law or rule, if known: _____

☐ Other (please explain): _____

INFORMATION ON RULE PETITION

(Attached pages)

The subject (or purpose) of this rule is:

The Washington CMV Project formally requests a new rule to the Washington Administrative Code mandating congenital cytomegalovirus (cCMV) screening for infants who do not pass their newborn hearing screening. Screening should be completed within the first three weeks of life. Several hospitals in Washington State have already created a standardized process to ensure infants are screened for congenital CMV in a timely manner after failing a newborn hearing screening.

Six states have adopted a mandate for cCMV. Of those six, four have included a provision to increase awareness about cCMV to high risk groups and the general population. An educational mandate could prevent CMV infections during pregnancy and save hundreds of infants a year.

The rule is needed because:

Congenital cytomegalovirus (cCMV) is a potentially devastating viral infection with a high incidence and low awareness. **It is the most frequent cause of congenital infection in the world with an incidence of 1 in 200 [1]. This is a higher incidence than any of the other 35 disorders on the Recommended Universal Screening Panel or on the Washington State Newborn Screening Panel.** Approximately 40-50% of the population is exposed to this virus before adulthood[2]. Since symptoms can be mild, individuals may unknowingly be infected and shed the virus.

Infants born with cCMV may present with such symptoms as thrombocytopenia, petechiae, hepatosplenomegaly, intrauterine growth restriction, microcephaly, ventriculomegaly, intracerebral calcifications, cortical or cerebellar malformations, chorioretinitis, or sensorineural hearing loss[3]. These symptoms range from relatively mild to severe and life-threatening. Only 10-25% of children are symptomatic at birth. Initial asymptomatic presentation does not negate future negative impact from the congenital infection. Among children with cCMV, 10-15% will develop sensorineural hearing loss[4]. It is the leading cause of non-genetic hearing loss in children. cCMV-related hearing loss has a varied presentation (progressive, fluctuating, stable, and with varying degrees of severity) making diagnosis and treatment difficult if not identified and closely monitored. Early detection and intervention of hearing loss can positively impact a child's development.

Symptomatic infants should receive a screen for possible cCMV infection. Asymptomatic presentation does not typically trigger screening unless there is concern for a mother's exposure while pregnant. However, the asymptomatic infants need attention of medical providers to ensure cCMV infection is not missed. Currently, 6 states have mandated newborn screening of cCMV. Washington is not one of them, but some hospitals are piloting newborn cCMV screening. Typically, screening is targeted to infants who do not pass their newborn hearing screening. To distinguish between a congenital or acquired infection, testing must be completed within the first 21 days of life. Treatment and monitoring should begin immediately when cCMV is confirmed, including anti-viral medications and regular hearing evaluations, with hearing amplification when needed.

While a universal screen would reach the most infants, a targeted approach has been shown to be cost effective and impactful in other states – Utah, Illinois, Iowa, New York, Virginia, and Connecticut.

The new rule would affect the following people or groups:
This virus is widespread and has serious impacts on children. The lack of awareness about cCMV increases the number of exposed infants. *In 2016, a study showed that 91% of women of childbearing age were unaware of CMV and its impact on their unborn child*[5]. Simple prevention strategies include frequent hand washing and avoiding kisses on the mouth or sharing utensils with children.

This rule would directly impact the infants born with congenital CMV and the families of those children. If an education mandate is also included, then pregnant women, their partners, medical providers, and women of high risk groups would also be affected.

References

1. Marsico, C., & Kimberlin, D. W. (2017). Congenital Cytomegalovirus infection: advances and challenges in diagnosis, prevention and treatment. Italian journal of pediatrics, 43(1), 38. https://doi.org/10.1186/s13052-017-0358-8
2. Centers for Disease Control and Prevention. 2020. About Cytomegalovirus (CMV). https://www.cdc.gov/cmv/overview.html
3. Rawlinson, W. D., Boppana, S. B., Fowler, K. B., Kimberlin, D. W., Lazzarotto, T., Alain, S., ... & Greenlee, J. (2017). Congenital cytomegalovirus infection in pregnancy and the neonate: consensus recommendations for prevention, diagnosis, and therapy. The Lancet Infectious Diseases, 17(6), e177-e188.
4. Cannon, M. J., Griffiths, P. D., Aston, V., & Rawlinson, W. D. (2014). Universal newborn screening for congenital CMV infection: What is the evidence of potential benefit? Reviews in Medical Virology, 24(5), 291–307. https://doi.org/10.1002/rmv.1790
5. Doutre, S. M. Barrett, T. S. Greenlee, J. & White, K. R. (2016). Losing Ground: Awareness of Congenital Cytomegalovirus in the United States. Journal of Early Hearing Detection and Intervention, 1(2), 39-48. DOI: 10.15142/T32G62

Suggested language for a new Washington Administrative Code:
Targeted Newborn Screening of Congenital Cytomegalovirus

[Language based on WAC 246-650-035: Screening for critical congenital heart disease.]

WAC 246-650-XXX: Targeted screening for congenital cytomegalovirus

(1) Prior to a hospital discharge of a newborn, who has failed a newborn hearing screening, the hospital shall ensure that:

(a) A licensed health care provider should perform a congenital cytomegalovirus screen on the newborn through saliva or urine specimen collection.

(b) Specimen collection should occur no sooner than 90 minutes after breastfeeding.

(c) Specimen collection should occur after a failed newborn hearing rescreen (failed second screen).

(ii) If the hearing rescreen is completed after hospital discharge, then the specimen collection should be completed within 24 hours and no sooner than 90 minutes after breastfeeding.

(d) Abnormal congenital CMV results should be reported in writing to the newborn's attending health care provider and parents/guardians.

(i) The newborn should also be referred for diagnostic audiologic testing.

(2)

(a) Except as provided in (b) of this subsection, a health care provider attending a birth outside of a hospital shall, between 24 hours of life and 21 days of life.

(i) perform a congenital cytomegalovirus screening after a failed hearing screening using saliva or urine specimen collection.

(ii) Specimen collection should occur no sooner than 90 minutes after breastfeeding.

(iii) Specimen collection should occur after a failed newborn hearing rescreen (failed second screen).

(iv) If the hearing rescreen is completed after hospital discharge, then the specimen collection should be completed within 24 hours and no sooner than 90 minutes after breastfeeding.

(v) Abnormal congenital CMV results should be reported in writing to the newborn's attending health care provider and parents/guardians.

(vi) The newborn should also be referred for diagnostic audiologic testing.

(b) If the health care provider does not perform the test required in (a) of this subsection because he or she does not possess the proper equipment, the health care provider shall notify the parents or guardians in writing that the health care provider was unable to perform the test and that the newborn should be tested by another health care provider no later than 24 hours after the failed newborn hearing screening and not past 21 days of life.

(3) A health care provider may not test a newborn as required by this section if the parents or guardians object to the test based on religious beliefs.

(4) If the health care provider does not perform a newborn hearing screening, the health care provider should notify the parents or guardians in writing that the health care provider was unable to perform the hearing screening and that the newborn should be tested by another health care provider no later than 24 hours after discharge. The written notification should also include that the child may need to be screened for congenital cytomegalovirus prior to 21 days of life if the newborn fails the hearing screening.