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## Exempt Action Final Regulation Agency Background Document

<b>Agency name</b>	Virginia Department of Health
<b>Virginia Administrative Code (VAC) citation(s)</b>	12 VAC5-80
<b>Regulation title(s)</b>	Regulations for Administration of the Virginia Hearing Impairment Identification and Monitoring System
<b>Action title</b>	Amend regulations to include screening for congenital cytomegalovirus in newborns who fail the newborn hearing screen
<b>Final agency action date</b>	
<b>Date this document prepared</b>	June 27, 2019

While a regulatory action may be exempt from executive branch review pursuant to § 2.2-4002 or § 2.2-4006 of the *Code of Virginia*, the agency is still encouraged to provide information to the public on the Regulatory Town Hall using this form. However, the agency may still be required to comply with the Virginia Register Act, Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1 VAC7-10), and the *Virginia Register Form, Style, and Procedure Manual for Publication of Virginia Regulations*.

### Brief Summary

*Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.*

Cytomegalovirus (CMV) is a common virus that infects people of all ages. Most people infected show no signs or symptoms; therefore, it may go undetected and be potentially harmful to infants born to mothers who are infected (congenital CMV). National statistics demonstrate that congenital CMV affects one in every 200 babies born each year. Furthermore, one in every five babies born with congenital CMV will develop permanent health problems including, but not limited to, hearing loss, vision loss, mental disability and failure to thrive.

Legislation enacted during the 2019 legislative session required the Virginia Department of Health to amend regulations governing newborn screening to include screening for congenital cytomegalovirus in newborns who fail the newborn hearing screen. HB2026 was approved by the Governor on March 18, 2019.

This regulatory action seeks to conform the regulations to changes in Virginia statutory law. Amendments were made to the following sections of the regulatory text:

- 12VAC5-80-10/Definitions: This section was amended to include acronyms and terms such as “CMV”, “cCMV”, “congenital cytomegalovirus” and “failed newborn hearing screening”.
- 12VAC5-80-80/Responsibilities of the Chief Medical Officer of Hospitals: Sections 6 and 7 were amended to change the notification time to the infant’s primary health care provider and to the department from two weeks to one week after birth. Section 7 was also amended to add subsection k to include congenital cytomegalovirus screening results in the required information to be provided to the department.
- 12VAC5-80-85/Responsibilities of Other Birthing Places or Centers: Sections 3 and 4 were amended to change the notification time to the infant’s primary health care provider and to the department from two weeks to one week after birth. Section 4 was also amended to add subsection k to include congenital cytomegalovirus screening results in the required information to be provided to the department.
- 12VAC5-80-90/Scope and Content of Virginia Early Hearing Detection and Intervention Program: Section B, subsection 3 was amended to include “results of screening for cCMV”.
- 12VAC5-80-150/Screening for congenital cytomegalovirus: This new section describes requirements related to screening for congenital cytomegalovirus.

### Mandate and Impetus

*Please identify the mandate for this regulatory change, and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, internal staff review, petition for rulemaking, periodic review, board decision, etc.). “Mandate” is defined as “a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part.”*

The 2019 General Assembly enacted legislation mandating the amendment of newborn screening regulations to include screening for congenital cytomegalovirus in newborns who fail a newborn hearing screen.

### Statement of Final Agency Action

*Please provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.*

Enter statement here

### Periodic Review Small Business Impact Review Report of Findings

*If you are using this form to report the result of a periodic review/small business impact review that is being conducted as part of this regulatory action, and was announced during the proposed stage, please indicate whether the regulatory change meets the criteria set out in Executive Order 14 (as amended, July 16, 2018), e.g., is necessary for the protection of public health, safety, and welfare; minimizes the economic impact on small businesses consistent with the stated objectives of applicable law; and is clearly written and easily understandable.*

*In addition, as required by § 2.2-4007.1 E and F of the Code of Virginia, include a discussion of the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation from the public; (3) the complexity of the regulation; (4) the extent to which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation.*

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There is a continued need for the regulations, as the provision of newborn screening services to babies born in the Commonwealth of Virginia is required by legislation. The amendment to include screening for congenital cytomegalovirus is necessary to protect the health, safety and welfare of Virginia's infants.

No public comments have been received.

The regulations are clearly written and easily understandable. The regulations do not overlap, duplicate or conflict with any known federal or state law or regulation.

Regulations are evaluated on an ongoing basis and these regulations were last amended in December 2013. The regulations underwent periodic review in February 2018.