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Periodic Review and Small Business Impact Review Report of Findings

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-110
VAC Chapter title(s)	Regulations for the Immunization of School Children
Date this document prepared	May 19, 2023

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 19 (2022) (EO 19), any instructions or procedures issued by the Office of Regulatory Management (ORM) or the Department of Planning and Budget (DPB) pursuant to EO 19, the Regulations for Filing and Publishing Agency Regulations (1 VAC 7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*.

Acronyms and Definitions

Define all acronyms used in this Report, and any technical terms that are not also defined in the "Definitions" section of the regulation.

No acronyms are used.

Legal Basis

Identify (1) the promulgating agency, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia or Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating agency to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.

Statutory authority to promulgate these regulations is granted to the State Board of Health by §§ 22.1-271.2 and 32.1-46 of the Code of Virginia. Penalties are established in § 32.1-27 of the Code of Virginia.

Alternatives to Regulation

Describe any viable alternatives for achieving the purpose of the regulation that were considered as part of the periodic review. Include an explanation of why such alternatives were rejected and why this regulation is the least burdensome alternative available for achieving its purpose.

There is a clear, specific and mandatory authority of the State Board of Health to promulgate the Regulations for the Immunization of School Children, therefore no alternatives are available that are advisable.

Public Comment

Summarize all comments received during the public comment period following the publication of the Notice of Periodic Review, and provide the agency’s response. Be sure to include all comments submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency. Indicate if an informal advisory group was formed for purposes of assisting in the periodic review.

This periodic review of the Regulations for the Immunization of School Children was published and the public comment period opened on 11/7/2022. The comment period ended on 11/28/2022. During that time, 639 comments were received. Of that, there are 602 unique IP addresses.

Commenter	Comment	Agency response
563 people via the Virginia Regulatory Town Hall	Against adding the COVID-19 Vaccine to the Regulations for the Immunization of School Children	No actions have been taken to by the Board of Health to add this vaccine.
53 people via the Virginia Regulatory Town Hall	Generally, against all mandated vaccines	School vaccine requirements ensure protection of children from vaccine preventable diseases, particularly in settings such as schools and childcare facilities where vaccine preventable diseases are likely to spread.
5 people via the Virginia Regulatory Town Hall	Against adding any new vaccines to the Regulations for the Immunization of School Children	As required by the Code of Virginia, the Board of Health will continue to review and amend the Regulations for the Immunization of School Children as necessary from time to time to maintain conformity with evidence-based, routinely recommended vaccinations for children.
5 people via the Virginia Regulatory Town Hall	Regulations need to address informed consent	As required by the National Vaccine Childhood Injury Act, all vaccine providers are required to give the appropriate Vaccine Information Sheet prior to every dose for all vaccines required for school entry in Virginia.
3 people via the Virginia Regulatory Town Hall	Unclear what the comments were suggesting for consideration or irrelevant to the subject of these regulations	Thank you for the comment.
2 people via the Virginia	Support continued allowance for both medical and religious exemptions	Thank you for the comment.

Regulatory Town Hall		
1 person via the Virginia Regulatory Town Hall	Supports continued allowance for medical exemption	Thank you for the comment.
1 person via the Virginia Regulatory Town Hall	Supports all current exemptions	Thank you for the comment.
1 person via the Virginia Regulatory Town Hall	Against the HPV Vaccine Requirement	Thank you for the comment.
1 person via the Virginia Regulatory Town Hall	Against the Tetanus Vaccine Requirement	Thank you for the comment.
1 person via the Virginia Regulatory Town Hall	Against power to exclude children who are not immunized against a disease that is subject of outbreak or epidemic of vaccine preventable disease	Thank you for the comment.
1 person via the Virginia Regulatory Town Hall	Suggests amending the penalty and fines associated with non-compliance with the vaccine schedule	Thank you for the comment.
1 person via the Virginia Regulatory Town Hall	<p>1) Amend the regulation to include informed consent. Per the manufacturers and as confirmed by Supreme Court, vaccines are unavoidably unsafe. That is why they gave the manufacturers freedom from liability. Risk of potential harm needs to be made clear.</p> <p>2) Amend to include medical exemptions; and protect doctors who issue medical exemptions from reprisal.</p> <p>3) Amend to include any diseases for which natural immunity can be demonstrated.</p> <p>4) The report should include injuries and deaths, not merely vaccine uptake.</p> <p>5) Remove the HPV vaccination.</p> <p>6) Allow children who are home schooled to be excluded from the vaccine requirements.</p>	Thank you for the comment.
1 person via the Virginia	Supports continued use of subject matter experts, technology, public	Thank you for the comment.

Regulatory Town Hall	input and a regular review cycle as it pertains to these regulations	
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Effectiveness

Pursuant to § 2.2-4017 of the Code of Virginia, indicate whether the regulation meets the criteria set out in the ORM procedures, including why the regulation is (a) necessary for the protection of public health, safety, and welfare, and (b) is clearly written and easily understandable.

The Code of Virginia, § 32.1-46, provides the Board of Health with the authority to promulgate the Regulations for the Immunization of School Children. These regulations specify immunizations that are required for attendance at public or primary elementary, middle or secondary schools, child care centers, nurseries, family day cares, and developmental centers in Virginia. These regulations are necessary as vaccine requirements ensure protection of children from vaccine preventable diseases, particularly in settings such as schools and childcare facilities where vaccine preventable diseases are likely to spread.

The regulations clearly detail 1) the immunizations that are required for school entry including spacing, ages, and intervals, 2) the process for exemption from the requirements, 3) the responsibilities of school and providers, and 4) penalties that apply for non-compliance.

Decision

Explain the basis for the promulgating agency's decision (retain the regulation as is without making changes, amend the regulation, or repeal the regulation).

If the result of the periodic review is to retain the regulation as is, complete the ORM Economic Impact form.

The Board of Health has a Final regulatory action (Action 5924) for the Regulations for the Immunization of School Children that is currently under Executive Branch Review. That action is simply amending the regulations to bring them into conformance with amendments to § 32.1-46 of the Code of Virginia from the passage of the Acts of Assembly Chapter 1223 (2020). The decision to retain as is as a result of this periodic review is based on the assumption that those amendments will go into effect and be published in the Virginia Register of Regulations.

The Board of Health has reviewed the regulations while considering 1) the current evidence-based, routinely recommended vaccinations for children, 2) Virginia's process for implementing school required vaccines, and 3) public comments received. Based on those factors, the Board of Health has determined that the Regulations for the Immunization of School Children will be retained as is without making changes.

Small Business Impact

As required by § 2.2-4007.1 E and F of the Code of Virginia, discuss the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation; (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. Also, discuss why the agency's decision, consistent with applicable law, will minimize the economic impact of regulations on small businesses.

There is a continued need for the regulation as it is essential to outline the requirements for immunization of school children, as required by Chapter 2 of Title 32.1 of the Code of Virginia, § 32.1-46.

The overwhelming majority of comments received concerning this regulation are in regard to adding the COVID-19 vaccine to the list of required immunizations for school entry. To date, the Board of Health has not taken any steps to add the COVID-19 vaccine to these regulations.

The regulation is clearly written and easily understandable.

The regulation does not overlap or duplicate any other federal or state law or regulation. Once the current Final regulatory action (Action 5924) is made effective and published, the regulation will not conflict with any other federal or state law or regulation.

Prior to the current Final regulatory action (Actin 5924), the regulation was last updated in 2019 through a Final regulatory action to conform to Chapter 222 of the 2019 Acts of Assembly. Retaining the regulations as is does not appear to cause an adverse economic impact on small businesses in the Commonwealth of Virginia.
