



Proposed Regulation Agency Background Document

Agency name	Department of Health (State Board of)
Virginia Administrative Code (VAC) citation	12 VAC 5 -110
Regulation title	Immunization of School Children
Action title	Update of the Regulations for the Immunization of School Children
Date this document prepared	September 30, 2008

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

In a short paragraph, please summarize all substantive changes that are being proposed in this regulatory action.

The proposed amendment to existing regulations will ensure compliance with legislation enacted by the 2006 and 2007 General Assemblies and with current immunization practices as recommended by the Advisory Committee for Immunization Practices, the American Academy of Pediatrics and the American Academy of Family Physicians (required by the Code of Virginia).

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., the agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

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.

Purpose

Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal, the environmental benefits, and the problems the proposal is intended to solve.

Regulations are necessary to ensure children are protected to the extent possible from vaccine-preventable diseases and to protect indirectly the health of Virginians. Legislation enacted by the 2006 Virginia General Assembly requires the regulations to be updated to reflect current immunization recommendations and also added two new required vaccines. Legislation enacted by the 2007 Virginia General Assembly added an additional new vaccine requirement. The regulations must be amended to bring them into conformance with the new legislation as well as with current immunization recommendations.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (More detail about these changes is requested in the "Detail of changes" section.)

Amendments to the current regulations will:

- Update and clarify definitions;
- Update childhood immunizations required for attendance at Virginia schools and day cares to include additional required vaccines and reflect current recommended immunization practices;
- Add requirements for demonstrating existing immunity to varicella; and,
- Update responsibilities of admitting officials.

Issues

Please identify the issues associated with the proposed regulatory action, including:

- 1) *the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;*
- 2) *the primary advantages and disadvantages to the agency or the Commonwealth; and*
- 3) *other pertinent matters of interest to the regulated community, government officials, and the public.*

If the regulatory action poses no disadvantages to the public or the Commonwealth, please so indicate.

The proposed regulations will ensure that children are protected to the extent possible from vaccine-preventable diseases and will indirectly protect the health of all citizens of Virginia. Disadvantages may include increased costs associated with providing additional required vaccines. Additional time may be needed for parents to obtain and providers to document required vaccines.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which are more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

There are no applicable federal requirements. The proposed regulations are written in response to the Code of Virginia 32.1-46 which requires children to be immunized and also requires an annual review of the section.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

All localities in Virginia would be affected by the proposed regulation.

Public participation

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.

The agency is seeking comments on the intended regulatory action, including costs and benefits and the potential impacts of this regulatory proposal. Also, the agency/board is seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments for the public comment file may do so by mail, email or fax to James B. Farrell, Director, Division of Immunization, Department of Health, 109 Governor Street, Room 314 West, Richmond, Virginia 23219; telephone (804) 864-8055 or email james.farrell@vdh.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last date of the public comment period. A public meeting will not be held to receive comments on this action.

Economic impact

Please identify the anticipated economic impact of the proposed regulation.

<p>Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures</p>	<p>The cost to the state will be to supply the additional doses of required vaccines to school-age children, including administration costs, for children receiving vaccines at local health departments, an on-going expense. Implementation of SB 116 in 2006 (Tdap requirement) depended on approval of funding; \$280,110/year was approved and will cover costs. In 2007, the legislature funded \$1.4 million/year to implement HB2035, which requires HPV vaccine for girls prior to sixth grade entry. This amount is expected to cover all costs. Minimal fiscal impact is expected as a result of increasing the required number of doses of tetanus, diphtheria, and pertussis containing (DTaP) vaccines from three to four. Current recommendations are for five doses and this vaccine is available at no cost to all children at local health departments. There will be very little fiscal impact as a result of requiring a second dose of mumps-containing vaccine; nearly all children already receive two doses when receiving the combination vaccine (MMR) to meet the current requirement for two doses of measles-containing vaccine. Requiring a second dose of varicella vaccine at kindergarten entry should also have minimal fiscal impact since a second dose of vaccine is currently being made available at no cost to all children under the age of 18 years at local health departments. Requiring pneumococcal vaccine for children less than two years of age (as added by SB116) is also expected to have minimal fiscal impact. Federal funds are adequate to supply vaccine to meet this requirement.</p>
<p>Projected cost of the regulation on localities</p>	<p>Local health departments may incur loss of revenue as a result of loss of the ability to charge for the office visit and for administration of the second dose of varicella vaccine to kindergarten students. Currently, this is approximately \$30 per dose of vaccine.</p>
<p>Description of the individuals, businesses or other entities likely to be affected by the regulation</p>	<p>Private health care providers may incur minimal additional costs for supplies to administer vaccines as well as minimal additional staff time to ensure children are appropriately vaccinated before school begins each year.</p>
<p>Agency’s best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than</p>	<p>All providers who immunize school-age children will be affected by these regulations. At most, it is estimated that this would affect about 4500 private providers and 135 public health clinics.</p>

500 full-time employees or has gross annual sales of less than \$6 million.	
All projected costs of the regulation for affected individuals, businesses, or other entities. Please be specific. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses.	The regulations will not place any additional reporting or recordkeeping requirements upon providers or schools beyond what is already required.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in §2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

The regulations are mandated by the *Code of Virginia*. The agency believes the regulations provide the best solution in response to the law.

Regulatory flexibility analysis

Please describe the agency’s analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

The agency believes that the proposed amendment to the regulations is the least burdensome option to meet the requirements of the Code and comply with current immunization practices as recommended by the Advisory Committee for Immunization Practices, the American Academy of Pediatrics and the American Academy of Family Physicians.

Public comment

Please summarize all comments received during public comment period following the publication of the NOIRA, and provide the agency response.

Commenter	Comment	Agency response
Alvin Spinner (X2)	We are in submit of the immunization initiative! The immunizations being discussed are a necessity! I am fully in support of	The agency agrees with Mr. Spinner’s comments.

	<p>this measure. We at http://www.couponwhale.com throw our full backing towards this initiative. (X2)</p>	
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Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

Parents are required by the *Code of Virginia* to have their children immunized. The regulations allow exemptions for medical reasons or if immunizations conflict with religious beliefs. All required vaccines are provided at no cost to parents at local health departments.

Detail of changes

Please detail all changes that are being proposed and the consequences of the proposed changes. Detail all new provisions and/or all changes to existing sections.

If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all changes between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.

For changes to existing regulations, use this chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
12 VAC 5-110-10			Clarify definitions (conditional enrollment, documentary proof, school, student, twelve months of age); add definition for immunization schedule
12 VAC 5-110-20			Add varicella, pneumococcal, and human papillomavirus disease as required by Code
12 VAC 5-110-30			Minor wording changes; no substantive changes
12 VAC 5-110-70			Add requirement for spacing, minimum ages and minimum intervals for vaccine doses to be in accordance with the immunization schedule
			Separate DTaP vaccine into component antigens (diphtheria, tetanus, pertussis) as they appear in the Code; change minimum number of doses required for each from 3 to 4; add Code requirement for a booster

			dose at 6 th grade entry; renumber vaccines.
			Edit polio and measles vaccines for clarity; remove unneeded language
			Add requirement for a 2 nd dose of mumps vaccine as recommended by the current immunization schedule
			Edit Hib vaccine requirements for clarity
			Add language to allow 2 doses of hepatitis B vaccine rather than 3 when FDA approved schedule and vaccine is used
			Add varicella vaccine as required by Code and recommended by the immunization schedule
			Add pneumococcal vaccine as required by Code
			Add human papillomavirus vaccine (HPV) for girls prior to entry into 6 th grade as required by Code
12 VAC 5-110-80			Add web address; remove unnecessary language
			Add criteria for demonstration of existing immunity to varicella
			Add authority to exclude unimmunized children when outbreak is identified
			Add exemption criteria for HPV vaccine
12 VAC 5-110-90			Add documentation of existing immunity to the category of students considered to be adequately immunized
			Clarify conditional enrollment period
			Add activities required for homeless students
			Delete the Table, "A Suggested Plan for Ensuring Compliance"
			Add information to allow admitting officials to submit required reports using a web-based reporting system
			Add requirement for admitting officials to ensure parent or guardian of females to be enrolled in the 6 th grade receive educational materials describing HPV vaccine
12 VAC 5-110-100			Edit criteria for documentary proof for out-of-state students
12 VAC 5-110-130			Update and clarify parental responsibilities; add penalties
FORMS			Update version of school entrance form

Enter any other statement here