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## Fast-Track Regulation Agency Background Document

<b>Agency name</b>	Department of Health, Office of Epidemiology
<b>Virginia Administrative Code (VAC) citation(s)</b>	12 VAC 5-110
<b>Regulation title(s)</b>	Immunization of School Children
<b>Action title</b>	Amend Regulations for the Immunization of School Children following periodic review
<b>Date this document prepared</b>	March 23, 2015

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

### Brief summary

*Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.*

Existing regulations will be updated in response to comments received as a result of periodic review. In addition, issues identified since the Regulations were last amended will be addressed. For example, pneumococcal conjugate vaccine should not be required for children entering kindergarten and demonstration of immunity to mumps through laboratory testing should be acceptable. Increasing use of electronic records requires modification to accommodate these technological changes.

### Acronyms and Definitions

*Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the “Definition” section of the regulations.*

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ACIP means the Advisory Committee on Immunization Practices, a group of medical and public health experts that develop recommendations on how to use vaccines to control diseases in the United States.

AAP means the American Academy of Pediatrics.

HPV means human papillomavirus.

### 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.*

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The State Board of Health approved this regulatory action on March 19, 2015.

### Legal basis

*Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person’s overall regulatory authority.*

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Statutory authority to promulgate these regulations is granted to the State Board of Health by sections 22.1-271.2 and 32.1-46 of the *Code of Virginia*.

### Purpose

*Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.*

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Regulations are necessary to ensure children are protected to the extent possible from vaccine-preventable diseases and to protect indirectly the health of all Virginians. Recent periodic review of existing regulations identified sections that are unclear or should be modified to address technological changes since the last regulatory action.

### Rationale for using fast-track process

*Please explain the rationale for using the fast-track process in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?*

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Some suggested changes are the result of comments received during the periodic review process. Additional changes are suggested to clarify issues that have been identified by others since the most recent amendments were enacted. None of the suggested changes will change any currently required immunizations or result in significant changes to current practice.

## Substance

*Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of changes" section below.*

Amendments to the current regulations will:

- Update and clarify definitions;
- Remove references to outdated versions of forms and ACIP schedules;
- Clarify that a printout of an electronic record can be accepted without the signature of a nurse or physician;
- Clarify that pneumococcal conjugate vaccine is not required for children enrolling in kindergarten;
- Clarify how long after the fourth birthday is allowable for those vaccines that are required to be administered on or after the fourth birthday;
- Add mumps to the list of diseases for which demonstration of immunity is acceptable;
- Clarify that the certificate of religious exemption must be notarized; 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 there are no disadvantages to the public or the Commonwealth, please indicate.*

The primary advantages to the agency and the public are that current regulations ensure that children are appropriately protected to the extent possible from vaccine preventable diseases. This also indirectly protects the health of all citizens of Virginia. Proposed changes should help clarify and simplify processes for providing and documenting immunizations required for school attendance. No disadvantages to the public or the Commonwealth are anticipated.

## Requirements more restrictive than federal

*Please identify and describe any requirement of the proposal which is 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 that 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.

### Regulatory flexibility analysis

*Pursuant to § 2.2-4007.1B of the Code of Virginia, 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.

### Economic impact

*Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.*

<b>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</b>	There will be very little, if any, fiscal impact as a result of the proposed changes.
<b>Projected cost of the new regulations or changes to existing regulations on localities.</b>	There will be very little, if any, fiscal impact as a result of the proposed changes.
<b>Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.</b>	Health care providers may be affected by the changes but the impact is expected to be minimal. Several changes are the result of provider suggestions.
<b>Agency’s best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses</b>	All providers who immunize school-age children will be affected by these regulations. At most it is estimated that this would affect about 4200 private

<p><b>affected.</b> Small business means a business entity, including its affiliates, that:  a) is independently owned and operated and;  b) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.</p>	<p>providers and 135 public health clinics.</p>
<p><b>All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs including:</b>  a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and  b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.</p>	<p>The Department of Health projects no additional costs as a result of these amendments.</p> <p>Changes will not place any additional reporting or recordkeeping requirements upon providers or schools beyond what is already required and may reduce the amount of time needed to comply with current requirements.</p>
<p><b>Beneficial impact the regulation is designed to produce.</b></p>	<p>Proposed changes are expected to clarify existing areas of confusion and may reduce the amount of time needed to comply with school immunization requirements.</p>

### 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.

### Public participation notice

*If an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall: 1) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register; and 2) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.*

### Periodic review and small business impact review report of findings

*If this fast-track is the result of a periodic review/small business impact review, use this form to report the agency's findings. Please (1) summarize all comments received during the public comment period following the publication of the Notice of Periodic Review and (2) indicate whether the regulation meets the criteria set out in Executive Order 17 (2014), e.g., is necessary for the protection of public health,*

safety, and welfare, and is clearly written and easily understandable. In addition, as required by 2.2-4007.1 E and F, please 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 the 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.

Commenter	Comment	Agency response
Craig Gill, Pfizer Inc.	Modify the Regulations to incorporate a requirement for all meningococcal vaccinations in accordance with ACIP recommendations.	The Agency agrees that this is good public health practice; however, an amendment to the <i>Code of Virginia</i> would be necessary in order to implement this requirement.
William C. Rees, MD President, VA Chapter, AAP	Require HPV vaccine for both males and females.	The Agency agrees that this is good public health practice; however, an amendment to the <i>Code of Virginia</i> would be necessary.
William C. Rees, MD	Begin routine meningococcal vaccine at age 11 or 12 with a booster at age 16.	The Agency agrees that this is good public health practice; however, an amendment to the <i>Code of Virginia</i> would be necessary.
Sandra Zieve, MD, Patient First	A printout of an electronic record should serve as proof of adequate immunization without the signature of a nurse or physician.	The Agency agrees that electronic records should be addressed as part of the proposed changes.
Sandra Zieve, MD	There is no provision that states how the school documents that the parent/guardian has reviewed materials about the HPV vaccine.	Requiring that a form be signed will require an amendment to the <i>Code of Virginia</i> .
Tia Campbell, MSN, Dept. of Education	The school form reference should be updated to the current version.	The Agency agrees and has incorporated this change in the proposed changes.
Douglas Mitchell, MD, Professor of Pediatrics	The section that refers to HPV vaccine in females should be changed to not be gender specific.	This change to the HPV section will require an amendment to the <i>Code of Virginia</i> .
Douglas Mitchell, MD	The current document refers to the 2010 version of the ACIP recommendations.	The Agency agrees that the current version of the ACIP schedule should be incorporated.

The regulation is required by the *Code of Virginia*; there is no conflict or overlap with federal law or regulations as there are none related to immunizations required for school attendance. The regulation was most recently amended in 2010 with the required periodic review initiated in 2014. Complaints received from the public were not about the complexity of the regulation but rather references to outdated forms (Campbell, Mitchell). Comments (Gill, Rees, Zieve) included requests for expansion of requirements or additional documentation rather than any reduction in the number of vaccines or documentation required for school attendance. Technology has expanded the use of electronic medical records that clearly identify the provider without the need for a signature. The Agency recognizes the need to modify the regulation in view of this; a comment was also received (Zieve) about this issue.

**Family impact**

*Please assess the impact of this 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 list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an emergency regulation, please list separately: (1) all differences between the pre-emergency regulation and this proposed regulation; and 2) only changes made since the publication of the emergency regulation.*

For changes to existing regulation(s), use this chart:

<b>Current section number</b>	<b>Proposed new section number, if applicable</b>	<b>Current requirement</b>	<b>Proposed change, intent, rationale, and likely impact of proposed requirements</b>
12VAC5-110-10		Refers to an outdated version of the school form – MCH 213F	Changes the reference to state “the most current version of Form MCH 213”
12VAC5-110-10		Requires a provider to sign or stamp a copy of the immunization record.	Adds that a signature is not required for the immunization record if the record is an electronic printout of a record from the provider’s electronic health system.
12VAC5-110-10		Defines “immunization schedule”	Changed to “immunization schedules” to clarify that all ACIP recommended schedules, including the catch-up information can be used to assess compliance.
12VAC5-110-70		Diphtheria, Tetanus, and Pertussis refer to a dose required after the fourth birthday	Language is added to clarify that the dose must be administered after the fourth birthday and prior to entering kindergarten to eliminate confusion about how long after the fourth birthday is acceptable to obtain this dose. This change is consistent with that already in place for the varicella and measles vaccines.
12VAC5-110-70		Acellular pertussis vaccine is currently required.	“Acellular” will be removed from the description so that children who received the whole cell version of the vaccine will



			not be required to receive additional unnecessary doses in order to be in compliance.
12VAC5-110-70		Pneumococcal conjugate vaccine is required for children up to the age of 60 months.	Clarifies that this vaccine is not required for enrollment in any grade level, kindergarten through grade 12 but only for children in day care or preschool.
12VAC5-110-80		States that no certificate of immunization is required if a Certificate of Religious Exemption is submitted to the admitting official	Clarifies that the affidavit must be appropriately completed and notarized to be acceptable.
12VAC5-110-80		Allows exemption to immunization requirement if student demonstrates antibodies against rubeola, rubella, or varicella in sufficient quantity to ensure protection.	Adds mumps to this list in order to be consistent with current ACIP recommendations. Changes the word "rubeola" to "measles" to conform to current practice and ensure consistency in the document.
12VAC5-110-90		Allows exemption to immunization requirement if student demonstrates antibodies against measles, rubella, or varicella in sufficient quantity to ensure protection.	Adds mumps to this list in order to be consistent with current ACIP recommendations.
12VAC5-110-90		Requires admitting officials to transfer records to the school to which a student is transferring within 30 days of transfer.	Reduces the time permitted to 10 days to better facilitate transfers and limit the time students may be unable to attend school
12VAC5-110-90		Requires admitting officials to submit a report summarizing the immunization status of students in his school.	Clarifies that the report should report student status as of the first day of school and changes the version of the form to state "most current".
12VAC5-110-90		Removes the reporting requirement specific to sixth grade.	Allows modifications to the reporting form to maintain consistency with any future requirements that may be implemented.

If a new regulation is being promulgated, use this chart:

Section number	Proposed requirements	Other regulations and law that apply	Intent and likely impact of proposed requirements