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Fast-Track Regulation Agency Background Document

Agency name	Department of Health, Office of Epidemiology
Virginia Administrative Code (VAC) citation(s)	12VAC5-110
Regulation title(s)	Regulations for the Immunization of School Children
Action title	Update Immunization Schedules and Clarify Responsibilities of School Admitting Officials.
Date this document prepared	April 7, 2017

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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.

The regulations will be amended to incorporate language from § 22.1-271.2 of the Code of Virginia to clarify that each admitting official is required to allow inspection of school immunization records by officials of the Department of Health.

The regulations will also be amended to reference the latest recommended immunization schedules.

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.

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.

CDC means the U.S. Centers for Disease Control and Prevention

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.

The State Board of Health approved this regulatory action on June 1, 2017.

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.

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.

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.

The regulations will be amended to clarify that immunization records shall be open to inspection by health department officials. Amendments are necessary to ensure children are protected to the extent possible from vaccine-preventable diseases and to protect the health of all Virginians. School officials must comply with the law, as stated in § 22.1-271.2 of the Code of Virginia, in regard to inspection of immunization records by health department officials. VDH annually reviews a random sample of school immunization records to ensure compliance with current requirements. VDH would also need to review school immunization records in the event of a vaccine-preventable disease outbreak. Local health department representatives have encountered increasing resistance from school officials. Most recently, at least three of the selected 600 sites initially refused to allow records to be reviewed as part of the annual immunization survey, despite instructions to de-identify records prior to review. If the proposed amendments are approved, failure to allow inspection of records could result in a decision to seek imposition of penalties (i.e. Class 1 misdemeanor) authorized by § 32.1-27 of the Code of Virginia.

Each year, the ACIP recommends changes to the immunization schedules that are subsequently published by the CDC and the AAP. The Regulations must also be amended to include the most recent schedules.

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?

Incorporating current statutory provision into the Virginia Administrative Code reinforces the duties of school admitting officials as currently required by law and does not change current practices.

Updating documents incorporated by reference is routine.

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 regulations will:

- Clarify required activities of school officials
- Update references to the most current version of the immunization schedule

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 amended regulations will help ensure that children are appropriately protected to the extent possible from vaccine preventable diseases. This also serves to protect the health of all Virginians. Proposed changes will clarify processes required for immunization record review and ensure that the most current recommendations are applied. 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 amendments are written in response to the Code of Virginia § 32.1-46 that requires children to be immunized and § 22.1-271 that defines school responsibilities.

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 amendments.

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 ACIP, the AAP 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.

<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>There will be very little, if any, fiscal impact as a result of the proposed amendments.</p>
<p>Projected cost of the new regulations or changes to existing regulations on localities.</p>	<p>There will be very little, if any, fiscal impact as a result of the proposed changes</p>
<p>Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.</p>	<p>No individuals or businesses not already subject to the current laws and regulations will be affected by these changes.</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,</p>	<p>All schools, including child care facilities and those with grades through 12 are included in the existing regulations. There are approximately 7,625 facilities including 5,012 licensed child care</p>

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.	facilities, 1,862 public schools and an estimated 750 private schools that are affected.
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: 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.	The Department of Health projects no additional costs as a result of these amendments.
Beneficial impact the regulation is designed to produce.	Proposed changes are expected to clarify existing areas of concern and to reference the most current immunization schedules.

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.

Regulations are mandated by the Code of Virginia. The Agency believes the regulations provide the best alternative 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 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

Not applicable

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. All families benefit when children are age-appropriately immunized according to the most recent recommendations. These changes will not affect this benefit.

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 follow the instructions in the text following the three chart templates below.

For changes to existing regulation(s), please use the following chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
12VAC5-110-10		Definition of “Immunization schedules” refers to an older version	Changes the reference from the 2015 schedules to 2017.
12VAC5-110-90		Discusses the responsibilities of admitting officials.	Adds a Section G describing the requirement that immunization records be open to inspection by health department officials.
12VAC 5- 110 Documents Incorporated by Reference		Current reference is to the 2015 recommended immunization schedules.	Updates the reference to the 2017 recommended schedules.