Form: TH-07 August 2022



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# Periodic Review and Small Business Impact Review Report of Findings

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-115
VAC Chapter title(s)	Virginia Immunization Information System
Date this document prepared	12/12/2023

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.

Board – State Board of Health VIIS – Virginia Immunization Information System

### **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.

The State Board of Health is the promulgating agency. Va. Code § 32.1-12 authorizes the Board to "make, adopt, promulgate and enforce such regulations and provide for reasonable variances and

exemptions therefrom as may be necessary to carry out the provisions of [Title 32.1] and other laws of the Commonwealth administered by it, the Commissioner or the Department."

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Va. Code § 32.1-46.01 requires the Board to establish the VIIS and to promulgate regulations to implement the VIIS.

### **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.

The Board is required, pursuant to § 32.1-46.01 to promulgate regulations to implement the VIIS, thus no viable alternative to these regulations for complying with that mandate exists.

#### **Public Comment**

<u>Summarize</u> 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.

No comments were received.

#### **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 regulations protect the public health, safety, and welfare of individuals in the Commonwealth of Virginia by ensuring that public health information associated with immunization records is kept in an efficient, inclusive, and secure system. This system is vital for ensuring immunization data is readily available to providers and impacted stakeholders to ensure they can provide timely and appropriate patient care.

The regulations set clear and easily understandable guidance for all providers and healthcare entities on the appropriate use of the VIIS by defining protocols related to authorized, participants, registration procedures, patient confidentiality, security, data entry and quality assurance, data release, data access, and updated forms.

#### **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

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The State Board of Health will amend the Virginia Immunization Information System Regulations to align the regulations with the Virginia Registrar of Regulations' Form and Style Requirements and to consider regulatory reduction where possible. Additionally, the agency will update the regulations to reflect current practice and administrative forms.

# **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 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. 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 necessary to comply with the mandate in § 32.1-46.01. The agency did not receive any comments or complaints from the public during the periodic review. The regulation is clearly written and easily understandable. The regulation does not overlap, duplicate, or conflict with any other federal or state law or regulation. The regulations were first promulgated in 2015, underwent Periodic Review in 2019 with a "Retain" decision, and were updated in January, 2022 to conform to Chapter 211 of the 2021 Acts of Assembly, Special Session I. Amending the regulations does not appear to cause an adverse economic impact on small businesses in the Commonwealth of Virginia.